

EXHIBIT 2

Transcript of Edward A. Lemmo, Ph.D.

1 (1 to 4)

October 24, 2022

	1		3
1	UNITED STATES DISTRICT COURT	1	A P P E A R A N C E S
2	EASTERN DISTRICT OF MICHIGAN	2	ON BEHALF OF THE PLAINTIFF, TRUTEK CORP.:
3	SOUTHERN DIVISION	3	STANLEY H. KREMEN, ESQUIRE
4	-----X	4	4 Lenape Lane
5	TRUTEK CORP., : Case No.:	5	East Brunswick, New Jersey 08816
6	Plaintiff/Counter-Defendant,: v. : 2:21-cv-10312	6	732.593.7294
7	BLUEWILLOW BIOLOGICS, INC. :	7	
8	Defendant/Counter-Plaintiff,: ROBIN ROE 1 through 10 :	8	ON BEHALF OF THE DEFENDANT, BLUEWILLOW
9	(fictitious names); ABC :	9	BIOLOGICS, INC.:
10	CORPORATION 1 through 10 :	10	LIANE M. PETERSON, ESQUIRE
11	(fictitious names), :	11	FOLEY & LARDNER
12	Defendants. :	12	3000 K Street, NW
13	-----X	13	Suite 600
14		14	Washington, D.C. 20007
15		15	202.672.5300
16		16	
17	Deposition of EDWARD A. LEMMO, PH.D.	17	ALSO PRESENT:
18	Conducted Remotely	18	JENNIFER PODIS - REMOTE TECHNICIAN
19	Monday, October 24, 2022	19	JOHN PARKMAN - VIDEOGRAPHER
20	10:00 a.m.	20	ASHOK WAHI
21		21	
22		22	
23	Job No.: 468438	23	
24	Pages: 1-283	24	
25	Reported by: Matthew Goldstein, RMR, CRR	25	
	2		4
1	Deposition of EDWARD LEMMO, PH.D., conducted	1	C O N T E N T S
2	remotely:	2	EXAMINATION OF EDWARD ANTHONY LEMMO PAGE
3		3	
4		4	By MS. PETERSON 8
5		5	E X H I B I T S
6		6	(Attached)
7		7	LEMMO DEPOSITION EXHIBIT PAGE
8		8	
9	Pursuant to Notice, before Matthew Goldstein,	9	Exhibit 2 Previously Marked, United 41
10	RMR, CRR, Notary Public in and for the State of	10	States Patent No. 8,163,802
11	Maryland.	11	Exhibit 12 Deposition Notice of Edward A. 12
12		12	Lemmo
13		13	Exhibit 13 Plaintiff's Opening Technical 54
14		14	Report
15		15	Exhibit 14 Plaintiff's Expert Report of 54
16		16	Edward A. Lemmo, Ph.D.
17		17	Responsive to and in Rebuttal
18		18	of Defendant's Opening Expert
19		19	Report of Mansoor M. Amiji
20		20	Exhibit 15 Report of Edward A. Lemmo, 55
21		21	Ph.D. in Reply to Defendant's
22		22	Expert Report on
23		23	Non-infringement
24		24	
25		25	Exhibit 16 Curriculum Vitae of Edward A. 66

Transcript of Edward A. Lemmo, Ph.D.

2 (5 to 8)

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	5		7
1 (Continued)			
2	E X H I B I T S		
3 Exhibit 18	Materials Reviewed for Report Preparation	216	
4 Exhibit 19	Skin Models for the Testing of Transdermal Drugs	274	
5 Exhibit 20	Formation and Stability of oil-in-water Nanoemulsions Containing Rice Bran Oil: In Vitro and In Vivo Assessments	275	
6 Exhibit 21	United States Patent Application Publication 2004/0071757	275	
7 Exhibit 22	Declaration of Dr. Edward Lemmo in Trutek v. Matrixx	276	
8			
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	6		8
1 THE REMOTE TECHNICIAN:	Thank you to		
2 everyone for attending this proceeding remotely,			
3 which we anticipate will run smoothly.			
4 Please remember to speak slowly. Do			
5 your best not to talk over one another. Please be			
6 aware that we are recording this proceeding for			
7 backup purposes.			
8 Any off-the-record discussions should be			
9 had away from the computer. Please remember to			
10 mute your mic for those conversations.			
11 Please have your video enabled to help			
12 the reporter identify who is speaking. If you're			
13 unable to connect with video and connecting via			
14 phone, please identify yourself each time before			
15 speaking.			
16 I apologize in advance for any			
17 technical-related interruptions. Thank you.			
18 THE VIDEOGRAPHER:	All right. Just a		
19 moment, please, and I'll get us on the record.			
20 Here begins media No. 1 in the			
21 videotaped deposition of Dr. Edward A. Lemmo in			
22 the matter of Trutek Corporation versus BlueWillow			
23 Biologics Incorporated, et al., in the United			
24 States District Court Eastern District of			
25 Michigan, Southern Division, Case			

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Transcript of Edward A. Lemmo, Ph.D.

3 (9 to 12)

October 24, 2022

	9		11
1	Q. And, Dr. Lemmo, have you had your	1 copy of the exhibit in the chat -- in the chat	
2	deposition taken before?	2 room. And so you can directly open up the	
3	A. I've never given a deposition.	3 document from there. Once we use a document, you	
4	Q. And I assume that would be no deposition	4 can open it from the chat, and then that way you	
5	in an expert capacity; correct?	5 can look at it separately on your own, as well.	
6	A. That's correct.	6 Okay?	
7	Q. And you've never had your deposition	7 A. Okay. Okay.	
8	taken in any other capacity, like in your personal	8 Q. And that will be available to everybody.	
9	capacity?	9 MR. KREMEN: Can I ask a question,	
10	A. No, unless you consider something like	10 Liane? We last time -- at the last deposition we	
11	traffic court.	11 agreed that we would have universal numbering of	
12	Q. Okay. Well, let me just run through a	12 exhibits. So that -- Exhibits 1 through 11 have	
13	few ground rules just to kind of familiarize you	13 already been numbered.	
14	14 with the process.	14 Is that okay with you?	
15	So I'll be asking you a series of	15 MS. PETERSON: Yeah, so we'll start with	
16	questions throughout the day. I would ask that	16 any new exhibits today with 12. Yep, that's the	
17	17 you wait until I finish with my question before	17 plan.	
18	18 responding. And, of course, I'll try to do the	18 MR. KREMEN: Sorry for interrupting.	
19	19 same when you're speaking. I'll try to wait to	19 MS. PETERSON: Okay. Let's go ahead and	
20	20 ask my next question until when you're done.	20 pull up the first exhibit. And this is going to	
21	21 Is that okay?	21 be the deposition notice of Dr. Lemmo. And we'll	
22	A. That's fine. Thank you.	22 mark that as Exhibit 12.	
23	Q. And, of course, it's really important	23 (Lemmo Deposition Exhibit 12 was marked	
24	24 that we try not to speak over each other because	24 for identification and attached to the	
25	25 that will help Matthew, our court reporter, take	25 transcript.)	
	10		12
1	down a clean and accurate record of the deposition	1 BY MS. PETERSON:	
2	today. Okay?	2 Q. Dr. Lemmo, have you seen Exhibit 12	
3	A. Thank you. Yes.	3 before?	
4	Q. I would also ask that you provide verbal	4 A. No, I have not.	
5	responses and answers to my questions rather than	5 Q. But you understand that you are	
6	shaking your head or nodding or saying "uh-huh."	6 appearing today pursuant to this deposition notice	
7	7 that's been marked as Exhibit 12?	7	
8	A. That's fine.	8 A. Yes.	
9	9 Q. Okay. And let me know at any point if	9 MS. PETERSON: We can take that down.	
10	10 you don't understand my question. I can rephrase	10 BY MS. PETERSON:	
11	11 it if you need me to. Otherwise, if you don't ask	11 Q. Dr. Lemmo, have you been retained as an	
12	12 me for clarification, I'll assume that you	12 expert, either in a testifying or consulting	
13	13 understand the question. Okay?	13 capacity, for any matter other than this matter in	
14	A. Yes. Thank you.	14 the past four years?	
15	15 Q. And, Dr. Lemmo, are you aware of any	15 MR. KREMEN: Objection to the form of	
16	16 reason why you would be unable to provide complete	16 the question.	
17	17 and truthful testimony during this deposition	17 THE WITNESS: Yes.	
18	18 today?	18 BY MS. PETERSON:	
19	A. No.	19 Q. And how many matters?	
20	20 Q. Okay. Now, one other kind of	20 A. In a -- as a consultant -- can you just	
21	21 housekeeping note, so Jennifer, our technician,	21 repeat the question?	
22	22 will be displaying the exhibits up on the screen,	22 Q. Have you been retained as an expert --	
23	23 and she can move through those if we need to look	23 I'll break it down.	
24	24 at any particular sections. And at the same time,	24 Have you been retained as a testifying	
25	25 when the exhibit is marked, she's going to put a	25 expert in any other matters in the past	

Transcript of Edward A. Lemmo, Ph.D.

4 (13 to 16)

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	13		15
1 four years, apart from this matter involving 2 Trutek?		1 Q. And do you know what patent was the 2 subject of those IPR proceedings?	
3 A. No.		3 A. I'm sorry, can you explain that?	
4 Q. Have you been retained as a consulting 5 expert to provide consulting expert analysis in 6 connection with any litigation matter in the past 7 four years?		4 Q. Well, you understand that an IPR 5 proceeding challenges the validity of a patent at 6 the United States Patent and Trademark Office; 7 correct?	
8 A. Yes.		8 A. Yes.	
9 Q. How many times?		9 Q. Do you know what patents were being 10 challenged in those IPR proceedings for which you 11 prepared declarations?	
10 A. One time.		12 A. I believe it was the Trutek '802 patent.	
11 Q. And who were the parties involved?		13 Q. And have you ever been retained by any 14 other entity or any other party to provide any 15 declaration or expert testimony in any other IPR 16 proceeding?	
12 A. Trutek and Matrixx Initiatives.		17 A. No.	
13 Q. And in connection with that prior matter 14 for Trutek involving Matrixx, did you prepare any 15 expert reports?		18 Q. What about a PGR proceeding?	
16 A. Yes.		19 A. I don't know what a PGR proceeding is.	
17 Q. How many?		20 Q. Okay. What about a reexamination, are 21 you familiar with that?	
18 A. I believe it was three. I may be wrong.		22 A. No.	
19 Q. And do you recall the general subject 20 matter of those three reports?		23 Q. So you haven't prepared any declarations 24 or provided any testimony in connection with a 25 reexamination either?	
21 A. Not offhand. I spoke about the 22 infringement of the patent, the patent by Trutek, 23 by Matrixx representing the Zicam product line.			
24 Q. And did all three reports that you 25 prepared in connection with the Trutek Matrixx	14		16
1 matter involving infringement of the Zicam 2 product?		1 A. No.	
3 A. It was the Zicam product infringing on 4 the technology of Trutek.		2 MR. KREMEN: Objection to the form of 3 the question.	
5 Q. Okay. But did all three of the reports 6 that you prepared, did they all relate to those 7 issues of infringement, or did they cover other 8 issues, as well?		4 BY MS. PETERSON:	
9 A. I don't remember.		5 Q. And to the best of your knowledge, are 6 you -- actually, let me back up.	
10 Q. And did you -- have you ever prepared a 11 declaration or some other type of sworn statement 12 for any prior litigation proceeding involving 13 Trutek?		7 Going back to those IPR proceedings for 8 which you were retained by Trutek, how many 9 declarations did you prepare?	
14 A. No.		10 A. Again, I believe it was either one or 11 two.	
15 Q. And what about apart from litigation, 16 have you prepared or signed any declarations or 17 expert reports in connection with any other 18 contested proceedings such as an IPR involving 19 Trutek?		12 Q. Okay. To the best of your knowledge, 13 are you aware if your proposed testimony or 14 opinions has ever been challenged or excluded by a 15 court or the patent office?	
20 A. Yes.		16 MR. KREMEN: Objection to the form of 17 the question.	
21 Q. How many times?		18 THE WITNESS: Can you rephrase that for 19 me?	
22 A. I believe once or twice.		20 BY MS. PETERSON:	
23 Q. And were those IPR proceedings or 24 something else?		21 Q. Just if you even know, to the best of 22 your knowledge, has your proposed opinions 23 contained in any of your prior reports or 24 declarations, has it ever been challenged in terms 25 of whether it's admissible?	
25 IPR proceedings.			

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5 (17 to 20)

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	17		19
1 A. Not to my knowledge.		1 by Trutek for the Matrixx matter?	
2 Q. And have you -- apart from the work that		2 A. I believe that was in 2019.	
3 you've done in connection with the prior Trutek		3 Q. And so prior to your retention in 2019,	
4 matter involving Matrixx and the current Trutek		4 as I understand it, you had no prior contact or	
5 matter involving BlueWillow, have you ever		5 any involvement with Trutek; is that correct?	
6 provided any consulting services in connection		6 A. That's correct.	
7 with any nasal antiseptic products?		7 Q. Or any employees of Trutek?	
8 A. No.		8 A. That's correct.	
9 Q. And so I would also assume that you		9 Q. Or any of the lawyers representing	
10 haven't prepared any reports or any declarations		10 Trutek?	
11 in connection with any analysis of any nasal		11 A. That's correct.	
12 antiseptic products for purposes of acting as a		12 Q. And who were you retained by for this	
13 testifying expert either?		13 matter?	
14 A. Correct.		14 A. Mr. Kremen.	
15 Q. And have you ever provided any		15 Q. Okay. Do you intend to testify at the	
16 consulting services for any other company apart		16 trial in this case?	
17 from these two matters with respect to		17 A. If necessary --	
18 compositions intended to be applied to the nasal		18 Q. And what about --	
19 passages for reducing the risk of infection by		19 A. -- yes.	
20 either bacteria or viruses?		20 Q. What about the Markman hearing, do you	
21 A. No.		21 intend to testify there?	
22 MR. KREMEN: Objection to the form of		22 A. If necessary, yes.	
23 the question.		23 Q. Have you been asked to?	
24 BY MS. PETERSON:		24 A. No.	
25 Q. And I assume you haven't been retained		25 Q. And will you be compensated for	
	18		20
1 as an expert to testify on any such matters		1 testifying at trial?	
2 either; is that correct?		2 A. I believe so, yes.	
3 A. That's correct.		3 Q. And what is your hourly rate that you're	
4 Q. Have you ever been retained by Trutek to		4 charging Trutek for this matter?	
5 provide any expert or consulting services on any		5 A. \$250 per hour.	
6 other matters beyond this BlueWillow and the prior		6 Q. And is that the same rate that you	
7 Matrixx matter?		7 charge for providing testimony, whether by	
8 A. No.		8 deposition or at trial?	
9 Q. Have you ever been retained by Trutek's		9 A. Yes.	
10 counsel, Mr. Stanley Kremen, previously on any		10 Q. Approximately how many hours have you	
11 other matter?		11 accrued to date working on this matter?	
12 A. No.		12 A. From the beginning you're referring to,	
13 Q. And have you ever been retained by		13 from when I was first retained in 2021?	
14 Trutek's other attorney, Keith Altman of the		14 Q. Yes.	
15 Altman law firm, on any other matter?		15 A. It's hard for me to say. I could give	
16 A. No.		16 you an estimate, if that's okay.	
17 Q. And what about Amirali Haidri -- I don't		17 Q. Yeah, give me an estimate.	
18 know if I said that name correct -- have you ever		18 A. I would say perhaps 60 hours.	
19 been retained by him or his firm to provide any		19 Q. And that's your best estimate sitting	
20 expert or consulting services?		20 here today?	
21 A. No.		21 A. That's my best estimate. It's difficult	
22 Q. Dr. Lemmo, when were you retained by		22 without information in front of me for how many	
23 Trutek for this matter?		23 times I either had to do reviews of material or	
24 A. I believe it was sometime in 2021.		24 had conversation with the attorney or any matter	
25 Q. And do you recall when you were retained		25 related to this.	

Transcript of Edward A. Lemmo, Ph.D.

6 (21 to 24)

October 24, 2022

	21		23
1	Q. Do you keep records of how much time you	1	A. Yes.
2	spend working on this matter?	2	Q. Did you watch the actual study that
3	A. Yes.	3	Dr. Ermakov conducted?
4	Q. And do you send invoices to Mr. Kremen?	4	A. No.
5	A. I send invoices directly to Trutek.	5	Q. Did he replicate that study for you when
6	Q. Okay. And whose attention are those	6	you visited him on October 14th, 2022?
7	sent to?	7	A. He did not replicate it.
8	A. They're sent to Ashok Wahi, and I copy	8	Q. And then just to confirm, I would expect
9	Mr. Kremen.	9	that since the only time you spoke to Dr. Ermakov
10	Q. Okay.	10	or met with him in person was about ten days ago,
11	Okay. So just generally speaking, I	11	11 would it be fair to say that you did not speak
12	don't want to know necessarily the subject of any	12	12 with him prior to submitting your opening report
13	conversations, but I would like to know the names	13	13 or your reply report in this matter?
14	of the people that you have spoken with in	14	A. Yes.
15	connection with your work on this matter involving	15	Q. And you did not view the equipment that
16	BlueWillow.	16	he used in this study prior to preparing any of
17	A. Conversations include Stan Kremen, Ashok	17	17 your expert reports either; correct?
18	Wahi, Alexi Ermakov, and Shane Burns.	18	A. Only on the report diagram where the
19	Q. Okay. Now, let's start with Alex	19	equipment is shown as a pictorial.
20	Ermakov. How many times have you spoken with him?	20	Q. Okay. So apart from what was contained
21	A. One time.	21	21 within Dr. Ermakov's report, you did not view the
22	Q. When was that?	22	22 equipment or visit his laboratory prior to
23	A. It was in October. I believe it was	23	23 preparing any of your expert reports?
24	October 14th.	24	A. Correct.
25	Q. Of what year?	25	Q. Okay. And what about Mr. Burns, how
	22		24
1	A. 2022.	1	many times did you speak with him?
2	Q. Okay. So a little over a week ago?	2	A. One time.
3	A. About two weeks ago, yes.	3	Q. And was that also an in-person visit?
4	Q. Okay. And that's the only conversation	4	A. Yes.
5	you've had with Dr. Ermakov.	5	Q. And where is he located?
6	A. Yes.	6	A. Pennsylvania.
7	Q. What was the subject matter of your	7	Q. And where did you visit him
8	conversation?	8	specifically?
9	A. To get clarification and also to see the	9	A. At his laboratory.
10	design of his study. I met him at his laboratory.	10	Q. And when was that visit?
11	Q. And where is his laboratory located?	11	A. About a week later. So it would be --
12	Rutgers University.	12	I'd have to look, but I think it was the 21st.
13	Q. And what were you seeking clarification	13	Q. And apart from that meeting with
14	on?	14	14 Mr. Burns on October 21st -- actually, let me
15	A. I wanted clarification on how he	15	15 confirm. That's October 21st, 2022?
16	conducted the measurement for surface charge.	16	A. 2022, correct.
17	Q. Okay. And then you also mentioned	17	Q. Okay. So apart from that one meeting
18	speaking to him or to see the design of his study.	18	18 with Dr. Burns on October 21st, 2022, is it
19	What did that involve?	19	19 correct that you had no other conversations with
20	A. To visit his laboratory and see the	20	20 Mr. Burns at any time regarding the subject matter
21	equipment itself.	21	21 of his testing?
22	Q. So you viewed the equipment that he	22	A. That's correct.
23	used?	23	Q. Did you ever meet with Dr. Ermakov or
24	A. Yes.	24	24 Mr. Burns to discuss the testing that they
25	Q. Did you watch it in operation?	25	25 conducted on the Matrixx products?

Transcript of Edward A. Lemmo, Ph.D.

7 (25 to 28)

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	25		27
1 A. No.		1 just to feel more comfortable that my	
2 Q. And no conversations, telephone or Zoom,		2 understanding of what testing they did was	
3 with Dr. Ermakov or Mr. Burns to discuss the		3 accurate.	
4 testing conducted on the Matrixx products?		4 Q. And apart from the meetings with	
5 A. No.		5 Mr. Burns and Dr. Ermakov in October of 2022, what	
6 Q. And what was the reason why you met with		6 else did you do to confirm your understanding of	
7 Mr. Burns on October 21st, 2022?		7 the accuracy of their testing?	
8 A. To, again, view his equipment, how he		8 A. The only other items was to review in	
9 conducted the test.		9 the literature how surface charge is measured.	
10 Q. And prior to your visit on October 21st,		10 Q. So just to make sure I understand.	
11 2022, you had not viewed the equipment or		11 Apart from your meetings with Dr. Burns --	
12 personally overseen how he conducted the test?		12 Mr. Burns and Dr. Ermakov to view the equipment	
13 A. Correct.		13 that was used and a literature search concerning	
14 Q. And when you visited him on		14 how surface charge is measured, you did not do	
15 October 21st, 2022, did he repeat or replicate the		15 anything else to confirm your understanding of the	
16 testing that he did?		16 accuracy of the Burns and Ermakov testing;	
17 A. He simply gave a demonstration of the		17 correct?	
18 equipment, but did not repeat the test.		18 A. That's correct.	
19 Q. And what equipment did he demonstrate?		19 Q. Now, you also mentioned that you're not	
20 A. He used a NanoCoulomb Meter, and he used		20 a specialist in that type of testing; is that	
21 a Faraday cup.		21 correct?	
22 Q. And was he actually testing anything, or		22 A. Yes.	
23 did he just show how the products operate?		23 Q. And so I assume that's why you didn't do	
24 A. He just showed how the product operates.		24 the testing yourself?	
25 Q. So he didn't --		25 A. Yes.	
	26		28
1 A. Or how the -- I'm sorry, how the		1 Q. Have you ever conducted that type of	
2 equipment operates.		2 testing of the surface charge measurements?	
3 Q. Okay. So he didn't take a particular		3 A. No.	
4 substrate and apply something to it and conduct		4 Q. Have you ever performed any testing to	
5 any measurements?		5 determine the conductivity of materials on a	
6 A. No.		6 substrate?	
7 Q. Okay. And so I will also assume that he		7 A. No.	
8 didn't demonstrate anything to you about how he		8 Q. Okay. Going backwards a little bit now.	
9 used the pig's skin in his experiments?		9 You also mentioned that you spoke with -- in	
10 A. No.		10 connection with your work on this matter, that you	
11 Q. And why -- well, did you ask to set up		11 also spoke with Mr. Kremen and Mr. Wahi; correct?	
12 these meetings with Dr. Burns -- or sorry,		12 A. Correct.	
13 Mr. Burns or Dr. Ermakov, or was it counsel's		13 Q. Do you recall speaking with anybody else	
14 suggestion?		14 other than those four individuals in connection	
15 A. I think it was a combination of getting		15 with your work on this matter?	
16 clarification to see what actually transpired in		16 A. No.	
17 the laboratory. So collaboration with both		17 Q. Okay. And how many times did you speak	
18 counsel as well as myself.		18 with Mr. Wahi?	
19 Q. And why did you feel it was necessary to		19 A. In person, two times.	
20 get that clarification?		20 Q. Okay. And how about either by telephone	
21 A. When you look at the reports of both		21 or by video?	
22 Dr. Ermakov and Mr. Burns, there are pictures and		22 A. Maybe eight times.	
23 descriptive terminology, but since I am not a		23 Q. That's a lot of meetings. I'm not going	
24 specialist in that particular area, I wanted to		24 to ask you to remember the details of every single	
25 see the equipment and how the equipment operates		25 one of them, but do you recall when the first	

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Transcript of Edward A. Lemmo, Ph.D.

8 (29 to 32)

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	29		31
1 meeting was?		1 prepared your expert reports in this matter?	
2 A. With Mr. Wahi?		2 A. Yes.	
3 Q. Yeah.		3 Q. Okay. And I assume the same is true	
4 A. Regarding this matter, he contacted me,		4 about the second in-person meeting to talk about	
5 I believe it was November of 2021. I may be		5 the Ermakov and Burns test, was that also within	
6 wrong, but I believe it was November.		6 the last couple of weeks?	
7 Q. And was that before or after you had		7 A. Yes.	
8 been retained for the matter?		8 Q. And what did you discuss with Mr. Wahi	
9 A. Yes.		9 concerning the Ermakov and Burns test?	
10 Q. And what was the subject matter of that		10 A. The question of measurement being	
11 discussion?		11 surface charge versus the statement that Dr. Amiji	
12 A. He approached me to utilize me as a		12 raised regarding conductivity.	
13 consultant expert to evaluate the matter.		13 Q. Okay. And what did you discuss?	
14 Q. And what matter are you referring to?		14 A. Simply to have a better understanding of	
15 A. The matter of Trutek versus BlueWillow.		15 the measurement technique, whether it was, in	
16 Q. Okay. Did Mr. Wahi ever contact you or		16 fact, a measurement of surface charge, or was it	
17 ask you to work as a consultant on any matter		17 conductivity that was measured.	
18 other than the ones directed to Matrixx and		18 Q. And would it be fair to say that you had	
19 BlueWillow?		19 that conversation because you were unsure of that	
20 A. No.		20 yourself based on your own experience?	
21 Q. Okay. And when was the most recent		21 A. Just to get reinforcement of the	
22 meeting that you had with Mr. Wahi?		22 subject.	
23 A. By telephone.		23 Q. And did that conversation change your	
24 Q. And when was that?		24 understanding in any way --	
25 A. By telephone, it was Friday the 21st.		25 A. No.	
	30		32
1 Q. And what was the purpose for that		1 Q. -- that you had prior --	
2 meeting?		2 A. No.	
3 A. He asked me if I needed any further		3 Q. So if you already had an understanding,	
4 clarification on the matter.		4 why did you feel it necessary to confirm it?	
5 Q. And did you?		5 A. Again, the question of -- that I like to	
6 A. No.		6 see things and also to ask questions of the people	
7 Q. Okay. And when were the two in-person		7 involved so that my understanding of the situation	
8 meetings that you had with Mr. Wahi?		8 is exactly the same as how they see it.	
9 A. Well, one they were several weeks back		9 Q. And did you have any conversations with	
10 to discuss, you know, at his facility just to,		10 Mr. Wahi prior to preparing your expert reports?	
11 again, get clarification and then on another		11 A. No.	
12 occasion to talk about the tests of Dr. Ermakov		12 Q. So all of your meetings with Mr. Wahi,	
13 and Mr. Burns.		13 whether by phone or video or in person, have been	
14 Q. Okay. And what clarification were you		14 sometime in just the last month or two of 2022; is	
15 seeking in that first meeting?		15 that correct?	
16 A. The understanding of the claims that are		16 A. Correct.	
17 utilized in the '802 patent by Mr. Wahi.		17 Q. But that would be other than the first	
18 Q. And that meeting you said was several		18 meeting --	
19 weeks ago?		19 A. Yes.	
20 A. Several weeks ago, yes.		20 Q. -- where Mr. Wahi contacted you about	
21 Q. So sometime in September or October of		21 the matter?	
22 2022?		22 A. Yes. I'm sorry I interrupted you. Yes,	
23 A. Probably. I'm not certain to the exact		23 that's correct.	
24 date again. I'd have to look that up.		24 Q. Okay. So as best you can remember, the	
25 Q. Okay. But it would have been after you		25 next meeting that you had with Mr. Wahi would have	

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9 (33 to 36)

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	33		35
1	been after you prepared your expert reports?	1	referenced throughout your report?
2	A. Yes.	2	A. Yes.
3	Q. Okay. What about your work on the	3	Q. Okay. And then with respect to
4	Matrixx matter, did you ever have any	4	commercial availability, you understand that
5	conversations with Mr. Wahi in connection with	5	NanoBio Protect is no longer being sold?
6	that matter?	6	A. Yes.
7	A. No.	7	Q. Okay. So you also mentioned a Trutek
8	Q. Okay. So apart from Mr. Kremen,	8	product that's known as NasalGuard; correct?
9	Mr. Wahi, Mr. Burns, and Dr. Ermakov, is there	9	A. Yes.
10	anybody else that you had any discussions with,	10	Q. So you're familiar with that product, as
11	whether by phone or video or in person, regarding	11	well?
12	the subject matter of this dispute?	12	A. Yes, I use it.
13	A. No.	13	Q. And how many products are within that
14	Q. Did you speak with anybody else at	14	line?
15	Trutek?	15	A. There are two products, NasalGuard
16	A. Well, not regarding the matter. There	16	scented and unscented, and then there's a spray
17	are people there, and so I did greet them, if	17	product.
18	that's what you're referring to. No. But no.	18	Q. And those are the products that are sold
19	The answer is no.	19	in the United States?
20	Q. No, I'm talking -- yeah, I'm talking	20	A. They're sold, I believe, in the United
21	about substantive conversations about the issues	21	States as well as overseas.
22	raised in the matter.	22	Q. Do you know if there are any other
23	A. No.	23	NasalGuard products sold overseas?
24	Q. Okay. Have you had any conversations	24	A. I'm not familiar with that.
25	with Mr. Haidri regarding this matter?	25	Q. Okay. Do -- are you familiar with the
	34		36
1	A. No.	1	formulation and the ingredients of the NasalGuard
2	Q. And did anyone else assist you in	2	product?
3	formulating your opinions provided in this matter?	3	A. Yes.
4	A. No.	4	Q. Do they all have the same formulation?
5	Q. I should also ask -- you mentioned the	5	A. Yes, with the exception of the scented
6	expert that's retained by my client, BlueWillow,	6	component. I'm referring primarily to the
7	and that's Dr. Amiji. Do you know him?	7	composition for the product that's sold in the
8	A. No, I do not.	8	tube.
9	Q. Dr. Lemmo, just very generally speaking,	9	Q. And what's different about the scented
10	in your understanding, what was the nature of your	10	composition?
11	assignment for this matter?	11	A. Just that it contains a scent as opposed
12	A. The nature of my assignment was to	12	to unscented.
13	provide expertise to demonstrate that the	13	Q. And do you know what that scent is?
14	BlueWillow product was infringing on the patent of	14	A. I don't use the scented product, I'm
15	Trutek, the '802 patent, in the claims that	15	sorry.
16	16 NanoBio makes and is commercially available.	16	Q. But other than the scent that's included
17	Q. I'm sorry, what do you mean by "the	17	in the scented formulation, it's your
18	claims that NanoBio makes"?	18	understanding that the formulation and composition
19	19 A. The product that's marketed by	19	19 of all the Trutek NasalGuard products are the
20	BlueWillow as NanoBio Protect provides claims in	20	20 same?
21	21 their advertising and on their packaging that	21	A. Yes.
22	22 resemble the Trutek product that is known as	22	Q. And are you familiar with the specific
23	23 NasalGuard.	23	23 ingredients that are used in NasalGuard?
24	Q. Okay. So you're referring to the	24	A. Yes.
25	statements from BlueWillow's website that are	25	Q. And how do you know that information?

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10 (37 to 40)

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	37		39
1 A. They're listed in the patent, the '802 2 patent. And, also, if you visit the NasalGuard 3 website and you click on the ingredients, they're 4 listed there, as well.		1 prepare for this deposition, I felt it necessary 2 to have a better understanding of those amounts.	
5 Q. And the ingredients that are listed on 6 the website, do they provide the specific amounts 7 of each ingredient that are included in the 8 NasalGuard product?		3 Q. But you didn't think it was necessary to 4 have an understanding of the amounts or the 5 percentages at the time that you formed your 6 opinions as stated in your reports?	
9 A. No.		7 A. Well, the percentages were available to 8 me at that time, but the amounts were not.	
10 Q. So it's just a list of ingredients?		9 Q. Okay. Let's back up. I thought you 10 said that you received the percentages two weeks 11 ago?	
11 A. Yes.		12 A. Yes, but the percentages are on the 13 website.	
12 Q. And do you know the specific amount of 13 each ingredient that's used in NasalGuard?		14 Q. Okay. Earlier you testified that the 15 website only has the list of ingredients, not the 16 percentages; is that correct?	
14 A. No.		17 A. Yes. All right. I misspoke, I'm sorry.	
15 Q. Have you ever asked for that 16 information?		18 Q. That's okay. I know it's -- it can be 19 tough keeping track of everything, especially when 20 I keep peppering you with questions. And, you 21 know, I apologize for that. If you need me ever 22 to restate my question just to make sure you 23 understand it, I'm always happy to do that. Okay?	
17 A. Excuse me?		24 A. Thank you. I appreciate that.	
18 Q. Have you ever asked Trutek for that 19 information?		25 Q. I also have the advantage of being able	
20 A. Yes.	38		40
21 Q. Did they provide it to you?		1 to see everything written out while you'll just 2 have to listen. So I know it's difficult.	
22 A. Yes. And percentages.		3 Okay. So let's just back up to make 4 sure I understand. The website includes the list 5 of ingredients, but not the percentages; correct?	
23 Q. Okay.		6 A. That's correct.	
24 A. Not the quantification. So, in other 25 words, what I'm saying is that of 100 percent,		7 Q. And you had that information about the 8 list of ingredients at the time of preparing your 9 expert reports; correct?	
1 they'll tell me how much of every ingredient is, 2 but not the specific quantities that are used.		10 A. That's correct.	
3 Q. Okay. So you have -- so you are aware 4 of the percentage of the entire composition for 5 each ingredient --		11 Q. Okay. You did not have the percentages 12 of the ingredients or the actual amounts of the 13 ingredients at the time of preparing your reports; 14 correct?	
6 A. Yes.		15 A. Well, I relied on the information that 16 was in the patent. So there are -- there is in 17 the Wahi '802 patent, there are tables that 18 include all of the ingredients or any permutation 19 of those ingredients in the ten different -- I'd 20 have to specifically, if I have it here, pull it 21 up so that I could take a look at it.	
7 Q. -- of NasalGuard?		22 Q. Yeah, we can pull that up right now.	
8 A. Yes.		23 A. Yeah.	
9 Q. And when was that information provided 10 to you?		24 MS. PETERSON: Can we pull up the 25 exhibit that was previously marked as Exhibit 2.	
11 A. Within the past two weeks.			
12 Q. So you did not have the information 13 about the percentage of the individual ingredients 14 within the NasalGuard products prior to preparing 15 your reports; correct?			
16 A. Only the information that was available 17 online.			
18 Q. And that would be just the list of 19 ingredients without their percentages?			
20 A. That's correct.			
21 Q. And why did you ask for the percentages 22 for the ingredients two weeks ago?			
23 A. For further clarification. These 24 matters are usually -- they're usually private or 25 considered confidential. And so in order to			

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11 (41 to 44)

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	41		43
1 THE REMOTE TECHNICIAN:	Yes, stand by,	1 A. Yes.	
2 Counsel.		2 Q. Okay. So you had this information --	
3 (Deposition Exhibit 2, Previously		3 certainly you had the '802 patent in your	
4 Marked.)		4 possession and considered it in forming your	
5 THE REMOTE TECHNICIAN:	It's on the	5 opinions as stated in your expert reports; right?	
6 screen.		6 A. Yes.	
7 BY MS. PETERSON:		7 Q. Okay. At the time you prepared your	
8 Q. Okay. And is it also -- Dr. Lemmo, if		8 reports, did you know which exact table of the	
9 you don't have a copy handy, if you go to the		9 '802 patent matched with the NasalGuard	
10 chat, you should be able to open up a copy of the		10 formulation?	
11 patent, as well, directly if it's easier for you		11 A. No.	
12 to scroll through it.		12 Q. Okay. And you also did not know the	
13 A. All right.		13 specific percentages of the ingredients in	
14 Q. Or we could ask Jennifer to scroll		14 NasalGuard at the time that you prepared your	
15 through to the tables. What would you prefer?		15 reports; correct?	
16 A. Yeah, if Jennifer can scroll through it,		16 A. Correct.	
17 it will make it easier for me because I'm opening		17 Q. Okay. Did you not think it was	
18 a lot of windows here, and I prefer not to. If		18 necessary or important to have an understanding of	
19 you scroll down --		19 the percentages of the ingredients in NasalGuard	
20 MS. PETERSON:	Yeah, I think we want to	20 at the time that you formed your opinions provided	
21 go to the fourth page of the PDF, starting with		21 in this matter?	
22 Column 5.		22 A. At the time I formed my opinion on the	
23 BY MS. PETERSON:		23 matter, I focused on specific things that were	
24 Q. Are these the tables you were referring		24 recited in the claims.	
25 to?		25 Q. Okay. But you didn't think it was	
	42		44
1 A. These are the tables I'm referring to,		1 important to have an understanding of the specific	
2 yes.		2 percentages of ingredients contained within	
3 Q. Okay. And where -- specifically which		3 NanoBio Protect in the course of forming your	
4 table contains the formulation for NasalGuard?		4 opinions; is that right?	
5 A. I don't have the exact reference to the		5 MR. KREMEN: Objection to the form of	
6 table for that because each is that it contains --		6 the question.	
7 it could contain this ingredient, the other		7 THE WITNESS: Can you just clarify that	
8 ingredient, et cetera. So I don't have that		8 for me, I'm sorry?	
9 information handy to say that it's Table 2 or		9 BY MS. PETERSON:	
10 Table 4 or whatever.		10 Q. So at the time that you formed your	
11 Q. Okay. But to your understanding, does		11 opinions as stated in your reports, you didn't	
12 at least one of these tables in the '802 patent		12 think it was important to understand the specific	
13 contain the exact list of ingredients in		13 percentages of ingredients contained within	
14 NasalGuard?		14 NanoBio Protect?	
15 A. I believe so.		15 A. Yes.	
16 Q. Okay. Now, if you look at the tables,		16 Q. And what about the ingredients for --	
17 you see that for many of the ingredients that are		17 oh, I'm sorry, I might have -- I asked a bad	
18 listed they're provided with a range, a percentage		18 question there. Let me try that again.	
19 range; correct?		19 At the time that you formed your	
20 A. Yes.		20 opinions as stated in your reports, you didn't	
21 Q. Okay. So is it fair to say that with		21 think it was important to understand the specific	
22 respect to the specific NasalGuard formulation,		22 percentages of ingredients contained within	
23 you don't know the precise percentage of the		23 Trutek's NasalGuard product?	
24 ingredients, but rather just what ranges are		24 A. Yes.	
25 reported in the tables of the '802 patent?		25 Q. And I think I had asked you that same	

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12 (45 to 48)

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	45		47
1 question with respect to NanoBio Protect. So let 2 me just clarify that.		1 matter relating to those issues of invalidity, for 2 example, in response to Dr. Amiji's report?	
3 When you prepared your -- formed your 4 opinions and prepared your expert reports, did you 5 know the specific ingredients that were contained 6 within NanoBio Protect?		3 A. I believe I did. 4 Q. And are all of your opinions on the 5 subject matters of -- or the issue of infringement 6 and patent validity, are those contained within 7 your three expert reports?	
7 A. Not the specific ingredients, the -- 8 there was one ingredient that I primarily focused 9 on and that was benzalkonium chloride.		8 A. Yes. 9 Q. Okay. Let's go ahead -- actually, let's 10 skip that for now.	
10 Q. Okay. But you were not aware of any of 11 the other ingredients contained within NanoBio 12 Protect when forming your opinions and preparing 13 your expert reports; correct?		11 Dr. Lemmo, what did you do to prepare 12 for your deposition?	
14 A. That's correct.		13 A. I reviewed the materials that are -- 14 that I wrote, and I reviewed the exhibits that you 15 provided or were provided to me by Mr. Kremen.	
15 Q. And would it be fair to assume, then, 16 that you were also not aware of the percentages of 17 the ingredients contained within NanoBio Protect 18 when forming your opinions and preparing your 19 expert reports?		16 Q. And what exhibits were those?	
20 A. Yes.		17 A. The list of exhibits that were -- that 18 we referred to such as this one, '802 patent, as 19 well as the statements by Dr. Amiji in his reports 20 and the other documents that accompanied that 21 group. So there was a list of exhibits.	
21 Q. Did your assignment in this matter 22 include anything other than assessing and 23 providing opinions on whether NanoBio Protect 24 infringes the '802 patent claims?		22 Q. Okay. The list of exhibits, is that 23 something that was contained in one of the expert 24 reports in this matter, or is that a list that was 25 prepared by Mr. Kremen?	
25 A. No.	46		48
1 Q. So you are not offering any opinions 2 concerning the validity of the '802 patent?		1 A. It was the list that was supplied by 2 Mr. Kremen.	
3 A. The validity of the '802 patent relative 4 to the claims that it makes?		3 Q. Okay. Did you review the deposition 4 transcript of Dr. Amiji to prepare for today's 5 deposition?	
5 Q. Well, you understand that a patent has a 6 number of claims at the end of it; right?		6 A. Yes.	
7 A. Yes.		7 Q. Now, the documents that were provided to 8 you that you reviewed in connection with your 9 preparation for this deposition, did you receive 10 any documents that you hadn't already seen before?	
8 Q. And those claims are what defines the 9 invention?		11 MR. KREMEN: Objection to the form of 12 the question.	
10 A. Yes.		13 THE WITNESS: I'm curious what you're 14 referring to. Because I did receive the patent, 15 which is one of the documents in the packet and 16 the statements from Dr. Amiji so that I could 17 provide a response to that. So I don't know if 18 there was anything else that you're referring to.	
11 Q. And is it your understanding that for an 12 infringement analysis, you have to compare those 13 claims and all of the elements to the accused 14 product to determine if they're all present?		19 BY MS. PETERSON:	
15 A. Yes.		20 Q. Okay. So -- well, I'll break it down. 21 So in preparation for your deposition, Mr. Kremen 22 provided you with some documents; correct?	
16 Q. And you also understand that those 17 patent claims could be found either by the patent 18 office or by a court or by a jury to be invalid 19 under any number of invalidity grounds?		23 A. Correct.	
20 A. Yes.		24 Q. Okay. Had you seen all of those 25 documents before in the course of your preparing	
21 Q. So, for example, like obviousness, 22 anticipation, enablement, are you familiar with -- 23 or have you heard of those terms before?			
24 A. Yes, I've heard of the terms.			
25 Q. So are you offering any opinions in this			

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13 (49 to 52)

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	49		51
1 your expert reports?		1 Q. So a clarification of his understanding	
2 A. Not all of them.		2 of the claim terms as the named inventor on the	
3 Q. Okay. What documents were new?		3 patent?	
4 A. Some of the documents related to the		4 A. My understanding of what he stated in	
5 terminology referring to the use of the word		5 his claims.	
6 "inhibition" or "inhibiting" versus the term		6 Q. Okay.	
7 "preventing."		7 A. So that we were -- I'm sorry. So that	
8 Q. Okay. Anything else?		8 we were on the same page, that I, in fact, read	
9 A. Offhand, I would have to look at my list		9 the claims accurately.	
10 of documents to be specific. I'm using two		10 Q. Okay. And in terms of what -- when you	
11 computers because I keep everything on electronic.		11 say what he stated in the claims, you're talking	
12 You have to forgive me.		12 about what Mr. Wahi stated in the claims as the	
13 Q. No problem.		13 named inventor on the patent?	
14 A. But I have to pull it up on the other		14 A. Yes.	
15 computer.		15 Q. Okay. Did you meet with Mr. Altman or	
16 The -- let's see, I have the notice of		16 have any phone conversations with Mr. Altman to	
17 deposition. I believe that was for Dr. Amiji.		17 prepare for your deposition?	
18 Q. Okay. And, Dr. Lemmo, just to be clear		18 A. I don't know Mr. Altman.	
19 here, I don't need you to read the list of		19 Q. Okay. You never --	
20 everything.		20 A. I've never spoken with Mr. Altman.	
21 A. Oh.		21 Q. Okay.	
22 Q. I'm just wondering if there was anything		22 A. I don't know who he is.	
23 new that you reviewed in preparation for your		23 MR. KREMEN: Are we on any line of	
24 deposition that you had not already considered		24 questioning that we can't interrupt for just a	
25 when forming your opinions and preparing your		25 break? Because we've been going for an hour. I	
	50		52
1 expert reports?		1 think Dr. Lemmo needs -- might need a little bit	
2 A. No.		2 of a break, unless you want to continue on.	
3 Q. Okay. Thank you.		3 MS. PETERSON: Yeah, let me just ask,	
4 Did you meet with anyone to prepare for		4 like, one or two more questions, and then that	
5 your deposition today?		5 will be a great breaking point.	
6 A. No.		6 BY MS. PETERSON:	
7 Q. Did you meet with Mr. Kremen at all to		7 Q. And then just to confirm, did you meet	
8 prepare for the deposition?		8 with or have any conversations with anybody else	
9 A. We spoke on the telephone.		9 at Trutek to prepare for your deposition?	
10 Q. Okay. How long did you speak with		10 A. No.	
11 Mr. Kremen on the telephone?		11 Q. And approximately how much time did you	
12 A. In total, maybe two to three hours.		12 spend reviewing the materials and the reports and	
13 Q. Was anybody else present for that		13 the deposition transcript to prepare for your	
14 conversation?		14 deposition today?	
15 A. No.		15 MR. KREMEN: Objection to the form of	
16 Q. Did you have any conversations with		16 the question.	
17 Mr. Wahi in preparation for your deposition?		17 THE WITNESS: Can you just spell it out	
18 A. I believe so, yes.		18 for me again?	
19 Q. And what did you discuss during that		19 BY MS. PETERSON:	
20 conversation?		20 Q. Yeah. How much time did you spend	
21 A. Again, it focused primarily on the '802		21 personally preparing for the deposition today?	
22 patent and the statements of the claims. Just the		22 A. Oh, to read everything -- I'm a slow	
23 clarification, once again.		23 reader, I'm sorry. To read everything and just to	
24 Q. The clarification of what exactly?		24 review, to refresh my memory, because some of the	
25 A. The terms that are used in the claims.		25 documents are a few months old, I would say	

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14 (53 to 56)

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	53		55
1 five hours. But that's not a solid five hours.		1 rebuttal of defendant's opening expert report of	
2 It's when I have the time to read different		2 Mansoor M. Amiji?	
3 documents, I did.		3 A. Yes.	
4 Q. Okay. Thank you.		4 MS. PETERSON: And if we could turn to	
5 MS. PETERSON: Why don't we go off the		5 page 14 of the PDF, please.	
6 record.		6 BY MS. PETERSON:	
7 THE VIDEOGRAPHER: We're going off the		7 Q. Is that your signature, Dr. Lemmo?	
8 record. The time is now 11:03 a.m.		8 A. That's my signature, yes.	
9 (Recess from the record.)		9 Q. And the report is dated August 23rd,	
10 THE VIDEOGRAPHER: We're back on the		10 2022?	
11 record. The time is now 11:13 a.m.		11 A. Yes.	
12 BY MS. PETERSON:		12 MS. PETERSON: And then let's mark as	
13 Q. Welcome back, Dr. Lemmo.		13 Exhibit 15 a copy of Dr. Lemmo's reply expert	
14 A. Thank you.		14 report.	
15 Q. Have you been asked to provide any		15 (Lemmo Deposition Exhibit 15 was marked	
16 opinions on anything else beyond what has been		16 for identification and attached to the	
17 contained in your three expert reports?		17 transcript.)	
18 A. No.		18 THE REMOTE TECHNICIAN: Stand by.	
19 Q. Okay. Now, you have submitted three		19 MR. KREMEN: Can we see a little more of	
20 reports in this case; right?		20 that.	
21 A. It was three or four. I forgot. But I		21 Can we see a little bit more of what's	
22 think it was three.		22 on that page because all I see is the caption.	
23 Q. Okay. So let's go ahead and mark and		23 MS. PETERSON: Yeah, can we scroll down	
24 identify those for the record.		24 a little bit on that page? There we go.	
25 MS. PETERSON: So we will mark as		25	
	54		56
1 Exhibit 13 a copy of Dr. Lemmo's opening report.		1 BY MS. PETERSON:	
2 (Lemmo Deposition Exhibit 13 was marked		2 Q. Dr. Lemmo, do you recognize Exhibit 15	
3 for identification and attached to the		3 as a copy of your reply expert report,	
4 transcript.)		4 specifically in reply to defendant's expert report	
5 THE REMOTE TECHNICIAN: Stand by.		5 on noninfringement?	
6 BY MS. PETERSON:		6 A. Yes.	
7 Q. Dr. Lemmo, do you recognize Exhibit 13		7 MS. PETERSON: And then if we could turn	
8 as your opening report?		8 to page 13 of the PDF.	
9 A. I believe so, yes.		9 BY MS. PETERSON:	
10 Q. And looking at page 16 of the PDF, is		10 Q. Is that your signature, Dr. Lemmo?	
11 that your signature?		11 A. Yes.	
12 A. I can only see the first page. If		12 Q. And this report was dated September 29,	
13 Jennifer can move that just to confirm it.		13 2022; correct?	
14 Yes, that's my signature.		14 A. Yes.	
15 Q. Okay.		15 Q. Okay.	
16 MS. PETERSON: And then let's mark as		16 MR. KREMEN: Liane, are we going to	
17 Exhibit 14 a copy of Dr. Lemmo's responsive		17 include -- add as an exhibit his declaration on	
18 report.		18 claim construction?	
19 (Lemmo Deposition Exhibit 14 was marked		19 MS. PETERSON: Yeah, I have that. I'll	
20 for identification and attached to the		20 bring it up later.	
21 transcript.)		21 MR. KREMEN: Okay. Fine. I just wanted	
22 THE REMOTE TECHNICIAN: Stand by.		22 to know. So we have four documents total from	
23 BY MS. PETERSON:		23 Dr. Lemmo; right?	
24 Q. Dr. Lemmo, do you recognize Exhibit 14		24 MS. PETERSON: I'm focusing on the	
25 as your expert report responsive to and in		25 expert reports currently, but later we'll look at	

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15 (57 to 60)

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	57		59
1 the declaration.		1 BY MS. PETERSON:	
2 MR. KREMEN: Sure.		2 Q. Well, in reaching the opinions and	
3 BY MS. PETERSON:		3 conclusions that you've stated in the report, did	
4 Q. Dr. Lemmo --		4 you have to make any assumptions about anything?	
5 MS. PETERSON: Actually, if we could go		5 MR. KREMEN: Objection to the form of	
6 back and pull up Exhibit 14 now. This is the		6 the question.	
7 responsive report.		7 THE WITNESS: I'm not really clear as	
8 And let's take a look at the second		8 far as what you're asking me.	
9 page. Yeah, right there. If we could scroll down		9 BY MS. PETERSON:	
10 a little bit to see the -- okay.		10 Q. Okay. And just to be clear then, this	
11 BY MS. PETERSON:		11 report contains all of your opinions on	
12 Q. So now, with respect to the validity of		12 invalidity, meaning you're not providing any --	
13 the '802 patent and responding to Dr. Amiji on		13 you have not been -- or you have not provided any	
14 these issues, Dr. Lemmo, you've offered four		14 opinions directed to anticipation of the '802	
15 opinions in this responsive report; correct?		15 patent?	
16 A. Yes.		16 A. There's a report that talks about those	
17 Q. And those would be the level of skill in		17 terms relative to anticipation and obviousness.	
18 the art, scientific and technical aspects of the		18 Is that what you're referring to?	
19 "hold" function of the '802 patent, enablement of		19 Q. I'm asking you if you have offered any	
20 the disclosure in the Rolf prior art		20 opinions in this report or formed any opinions as	
21 publication --		21 shown in this report on the issue of anticipation?	
22 MS. PETERSON: And then if we scroll		22 A. I believe I did.	
23 down to the next page.		23 Q. Okay. Can you identify where that is?	
24 BY MS. PETERSON:		24 A. I'd have to scroll through the report.	
25 Q. -- the fourth topic is the relevance of		25 I'm only seeing -- I'm only seeing a short form	
	58		60
1 the commercial success of Trutek's products.		1 here. And I believe this is -- I can't scroll	
2 A. Yes.		2 through the report.	
3 Q. Those are the four opinions that you've		3 THE REMOTE TECHNICIAN: Counsel, I can	
4 offered in response to Dr. Amiji's opening report?		4 give him access to --	
5 A. Yes.		5 MS. PETERSON: Okay. That's fine.	
6 Q. Does Exhibit 14, your responsive report,		6 THE REMOTE TECHNICIAN: -- control, and	
7 contain all of the opinions that you have formed		7 he can scroll on his own --	
8 directed to the issues of validity of the '802		8 MS. PETERSON: Sure.	
9 patent?		9 THE REMOTE TECHNICIAN: -- if that works	
10 A. Yes.		10 for you.	
11 Q. And does your responsive report contain		11 Dr. Lemmo, will that work for you?	
12 a complete statement of all the bases for your		12 THE WITNESS: We'll try.	
13 opinions?		13 THE REMOTE TECHNICIAN: Okay. Stand by.	
14 A. Yes.		14 Now, you should be able to with your	
15 Q. Are there any statements in your		15 mouse take control. If you click on the document,	
16 responsive report that constitute the opinions of		16 you should be able to take control.	
17 others?		17 THE WITNESS: A person having ordinary	
18 A. No.		18 skill. We talked about the "hold" function. Just	
19 Q. And did you make any assumptions in		19 bear with me with this as I scroll through it.	
20 formulating the opinions provided in your		20 This is the discussion of Rolf and what	
21 responsive report?		21 commercial success indicates.	
22 MR. KREMEN: Objection to the form.		22 Okay. Okay. I think I'm getting that	
23 THE WITNESS: I don't understand what		23 confused with another document where I do talk	
24 you mean by "assumption."		24 about anticipation and obviousness.	
25		25	

Transcript of Edward A. Lemmo, Ph.D.

16 (61 to 64)

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	61		63
1	BY MS. PETERSON:	1	A. No, I drafted them myself.
2	Q. Okay. What document is that? Because I	2	Q. Are there any portions of any of the
3	haven't seen that in any of your reports.	3	three reports that you did not draft yourself?
4	A. All right. No, I think Dr. Amiji talks	4	A. No.
5	about it, and I think I responded to it.	5	Q. And I'm sorry, I might be going back
6	Q. Okay. That's correct. Dr. Amiji did	6	over something we already covered, but just to
7	talk about anticipation --	7	make sure, you are aware that Trutek has retained
8	A. Yeah.	8	Mr. Haidri to also opine on issues relating to
9	Q. -- and obviousness.	9	invalidity.
10	A. Yes.	10	Is that your understanding?
11	Q. However, you are not responding to those	11	A. Yes.
12	issues of anticipation or obviousness in your	12	Q. Okay. Did you have any conversations or
13	responsive report marked as Exhibit 14; correct?	13	any meetings with Mr. Haidri when either he was
14	A. That's correct.	14	working on his responsive report or when you
15	Q. Okay. And you also did not form any	15	prepared your responsive report?
16	opinions responding to Dr. Amiji on issues of	16	A. No, I've never had a conversation with
17	Section 101 or otherwise known as subject matter	17	Mr. Haidri.
18	eligibility; is that correct?	18	Q. Okay. Have you reviewed Mr. Haidri's
19	A. That's correct.	19	report?
20	Q. And you also did not form any opinions	20	A. No.
21	responding to Dr. Amiji on issues under	21	Q. Do you know why you were asked to only
22	Section 112, including written description,	22	address certain of the issues in response to
23	utility, or enablement; is that correct?	23	Dr. Amiji on issues of invalidity?
24	A. That's correct.	24	MR. KREMEN: Objection to the form of
25	MR. KREMEN: Objection; calls for a	25	the question.
	62		64
1	legal conclusion.	1	THE WITNESS: Maybe you could rephrase
2	MS. PETERSON: We can take that exhibit	2	that for me.
3	down.	3	BY MS. PETERSON:
4	BY MS. PETERSON:	4	Q. Okay. Well, you understand that
5	Q. Now, you've submitted two expert reports	5	Dr. Amiji offered opinions on invalidity of the
6	on issues of infringement. That would be your	6	'802 patent; right?
7	opening report and your reply report; right?	7	A. Yes.
8	A. Yes.	8	Q. And you reviewed his report; correct?
9	Q. Okay. And do those two reports, your	9	A. Yes.
10	opening report and reply report, contain all of	10	Q. But you did not form opinions in
11	the opinions you formed on issues directed to	11	response to each of the issues raised by
12	infringement?	12	Dr. Amiji; correct?
13	A. Yes.	13	A. Correct.
14	Q. Do the opening and reply reports contain	14	Q. Okay. Do you know why you were asked to
15	a complete statement of all of the bases for your	15	only address those four issues that are contained
16	opinions?	16	in your responsive report?
17	A. Yes.	17	MR. KREMEN: Objection to the form of
18	Q. And are there any statements or opinions	18	the question.
19	in your opening report or reply report that	19	THE WITNESS: Maybe you could rephrase
20	constitute the opinions of others?	20	that for me again, sorry.
21	A. No.	21	BY MS. PETERSON:
22	Q. Dr. Lemmo, did you draft your three	22	Q. Why did you only respond to those four
23	expert reports that we just marked as Exhibit 13,	23	issues in your responsive report?
24	14, and 15 by yourself, or did you have	24	A. I think they were most important. Those
25	assistance?	25	were the four most important issues.

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17 (65 to 68)

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	65		67
1 Q. Those were the four most important 2 issues in terms of having a disagreement with 3 Dr. Amiji?		1 Exhibit 16 as a copy of your CV?	
4 MR. KREMEN: Objection to form.		2 A. Yes.	
5 THE WITNESS: If we could just take a 6 look at those four, not necessarily a disagreement 7 with Dr. Amiji, but to express my opinion.		3 Q. Do you have any changes to make to it, 4 or is it current?	
8 BY MS. PETERSON:		5 A. That's current.	
9 Q. Okay. So I just want to understand the 10 basis for your understanding that those were the 11 four most important issues. Why were they 12 important to you?		6 Q. Do you have any patents?	
13 A. If we could -- you know, if we could 14 pull those up, this way I could --		7 A. No.	
15 Q. Yeah, let's go back to Exhibit --		8 Q. And have you ever published any 9 articles?	
16 A. That would be great.		10 A. Yes.	
17 Q. Yeah.		11 Q. Scientific papers?	
18 A. Yeah, that would be great.		12 A. Yes.	
19 MS. PETERSON: Exhibit 14 -- Exhibit 14, 20 page 2, please.		13 Q. Okay. Are those publications listed in 14 your CV? I don't think they are.	
21 THE WITNESS: Yeah, that will make it 22 easier for me. Okay.		15 A. I don't think so.	
23 BY MS. PETERSON:		16 Q. Okay. Approximately how many papers 17 have you published over the last -- or in general, 18 do you know a rough number?	
24 Q. Actually, you know what, let me ask you 25 another question first. For these four issues you		19 A. Not that many. The publications related 20 to my degrees, my dissertation research, as well 21 as my master's degree, and also publications that 22 were either in the form of newsletters, booklets 23 that were asked of me by corporations to write or 24 internal documents. So in total, I would say 10 25 to 15 would be a maximum number.	
	66		68
1 addressed in your responsive report, did you 2 identify these issues, or were you asked by 3 counsel to provide your opinion on these four 4 topics?		1 Q. And what about any -- like any 2 conferences, did you -- have you ever prepared or 3 given any abstracts or any presentations at 4 conferences within your field of study?	
5 A. I think it was a combination of both.		5 A. Yes.	
6 Q. Did counsel for Trutek ask you to 7 provide opinions on any other issues beyond these 8 four with respect to the invalidity of the patent?		6 Q. Approximately how many?	
9 A. Not to my recollection, no.		7 A. A presentation of my research work for 8 my Ph.D., as well as my research work on my 9 master's degree. I've also served as an invited 10 speaker at various conferences, professional 11 meetings. But, again, it's not -- it's based upon 12 materials that were part of the conference. So, 13 for example, I would give lectures on various 14 aspects of nutrition or aspects of the corporate 15 sector and how science and regulatory affairs are 16 integrated into the development of products.	
10 Q. Okay. Yeah, I think that answers my 11 question.		17 Q. Okay. And just to confirm, those aren't 18 listed in your CV either; right?	
12 MS. PETERSON: So we can take that down.		19 A. That's correct. I did not list that.	
13 THE WITNESS: Okay.		20 Q. Okay. So, Dr. Lemmo, I believe you 21 described yourself as a consumer health care 22 corporate consultant; is that right?	
14 MS. PETERSON: Let's mark as another 15 Exhibit -- we'll mark this as Exhibit 16. Let's 16 pull up a copy of Dr. Lemmo's CV.		23 A. Yeah, a consumer health care related to 24 products that are sold over-the-counter, OTC 25 products primarily.	
17 (Lemmo Deposition Exhibit 16 was marked 18 for identification and attached to the 19 transcript.)			
20 MS. PETERSON: Jennifer, this is 21 identified as No. 6 in the file.			
22 THE REMOTE TECHNICIAN: Yes, I see it. 23 Thank you.			
24 BY MS. PETERSON:			
25 Q. Okay. Dr. Lemmo, do you recognize			

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18 (69 to 72)

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	69		71
1	Q. Okay. And would that primarily relate 2 to products such as nutritional supplements and 3 vitamins, so products in those categories?	1	had over that time frame, from 2007 to the 2 present?
4	A. Yes, those as well as some other 5 categories, primarily in the area of homeopathic 6 medicines and some other roles that I've been 7 involved in in the -- for example, in BioBalance, 8 a probiotic product that was used in the treatment 9 of specific kinds of conditions, gastrointestinal 10 disorders.	3	A. Consultant -- well, the only one that's 4 not there is Trutek. So in 2011, I served as a 5 consultant for Matrixx Initiatives.
11	Q. And what do you -- just so we can be 12 clear on terminology, what are you referring to as 13 homeopathic medicines?	6	Q. Okay.
14	A. Homeopathic medicine is the use of 15 natural remedies. They're extracts of botanicals. 16 These are used as tinctures. And in Eastern 17 European traditions, homeopathy is a very 18 significant part of medicine. And so I've given 19 lectures on homeopathic medicine, you know, both 20 in a corporate setting as well as in professional 21 meetings.	7	A. And then the -- that's correct. There's 8 no other consulting that was done other than those 9 two. Because it was mostly academic work that I 10 did.
22	Q. Okay. And you have a bachelor's degree 23 in chemistry; right?	11	Q. Okay. So from 2011 to the present, you 12 have the consulting work obviously with Trutek, 13 and then the rest of your, I guess we'll just say 14 employment, for use of a better term, that's been 15 with respect to your academic teaching 16 assignments?
24	A. That's correct.	17	A. That's correct. Because for the most 18 part I've been retired since 2000 -- let's see, 19 2018. So I reached retirement age in 2018. And 20 so I simply do consulting work at this point. I 21 no longer do academic work.
25	Q. And a master's and a Ph.D. in nutrition	22	Q. Okay. And then have you done any other 23 consulting work since 2018 apart from the 24 consulting services provided to Trutek?
	70		72
1	science; right?	1	Q. Okay. So looking at this most recent
2	A. That's correct.	2	corporate consulting experience you have listed
3	Q. Okay. And it looks like you have for 4 the last 15 years, primarily, you've been acting 5 as a consultant for a consumer health care 6 corporate consultant?	3	3 for Matrixx, I see there's one item identified as
7	A. Yes, and also working in academia, you 8 know, as an either part-timer or full time for a 9 college or university in the vicinity.	4	4 relating to an oral zinc product; is that correct?
10	Q. Okay. And those -- the college teaching 11 experience that you have, that is listed in your 12 CV; right?	5	A. Yes, that's correct.
13	A. Yes.	6	Q. Okay.
14	Q. Is that complete?	7	MS. PETERSON: If we could go back and
15	A. Yes, it is.	8	look at the first page.
16	Q. Okay. Now, looking --	9	BY MS. PETERSON:
17	MS. PETERSON: Could we scroll down to 18 the third page.	10	Q. So the consumer health care corporate 11 consultant work from 2007 to the present, that's 12 been focused on the Matrixx assignment and the 13 work with Trutek; right?
19	BY MS. PETERSON:	14	A. Correct. Or if a colleague or someone I 15 knew in the corporate sector reached out to me to 16 review a product and just to provide them with 17 some guidance, particularly for claim construction 18 or regulatory affairs, it might have been 19 something that surfaced but it was nothing 20 significant and I did not really include that.
20	Q. Do you see there's a heading here that 21 says "Corporate Consulting Experience"?	21	Q. Okay. You provided consulting services 22 for claim construction? Did I hear you correctly?
22	A. Yes.	23	A. Yes, claim construction on a product.
23	Q. Now, I only see one consulting 24 assignment here listed within that time frame 25 after 2007. Is that the only consulting job you	24	Primarily, if a company wants to market a product, 25 I'll use an example of a dietary supplement, there

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19 (73 to 76)

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	73		75
1 are guidelines that the company must follow in 2 order to make the claim that it has adequate 3 substantiation attached to the claim. 4 Q. I understand. Okay. 5 A. So that's essentially it. 6 Q. Okay. Thank you. 7 Okay. So then prior to that, you were 8 with BioBalance Corporation, and that involved the 9 probiotic product you mentioned earlier? 10 A. Yes. 11 Q. Okay. And then it looks like you were 12 with Wyeth Consumer Healthcare in product 13 development for about six years; right? 14 A. That's correct. Until the company was 15 purchased by Pfizer. 16 Q. Okay. And your work at Wyeth with 17 respect to product development, that was focused 18 on, it looks like, a few brands: Solgar, Centrum 19 and Caltrate; correct? 20 A. That's correct. 21 Q. Those are vitamins or calcium 22 supplements? 23 A. That's correct. 24 Q. And then when you say that you managed 25 the product development of those brands, what did		1 new formulations or products in the laboratory? 2 MR. KREMEN: Objection to form. 3 THE WITNESS: Well, it did include 4 supervision of the laboratory, as well as the 5 formulation of the product within the 6 manufacturing sector. So if I could elaborate, my 7 function was in the creation of a new product to 8 work with both the analytical segment of the 9 company, and those were more of the pharmaceutical 10 people, as well as the manufacturing element of 11 the concept so that the concept, the idea, would 12 come to fruition as a finished product. 13 BY MS. PETERSON: 14 Q. Okay. Thank you. 15 And it looks like prior to that you were 16 with General Nutrition Centers, GNC? 17 A. Yes. 18 Q. And your work there was directed to 19 nutritional supplements? 20 A. Primarily, yes. The General Nutrition 21 Centers, Incorporated, the retail outlets coast to 22 coast, had a major presence particularly relative 23 to the passage of the Dietary Supplement Health 24 and Education Act, known as DSHA, and the company 25 needed representation with respect to that	
1 that involve? 2 A. Well, it involves either the creation of 3 new product -- if I could just backtrack, Solgar 4 Vitamin and Herb Company was acquired by Wyeth 5 Consumer Healthcare around the time -- I believe 6 it was 1998, and I was hired by the company to 7 kind of head up their scientific division for that 8 division. 9 In addition to that, I was employed by 10 Wyeth in their business development unit in the 11 evaluation any products that would be coming into 12 the OTC area as one of the scientists who worked 13 on that team. 14 So I provided expertise, opinions on the 15 validity of the products that would be presented 16 to be incorporated into the portfolio, as well as 17 if the company was interested in doing 18 acquisitions of the business or acquisition of a 19 product, I would be on that review team. 20 Q. Okay. And so that work focused on 21 evaluating the technical aspects of the products? 22 A. Yes. 23 Q. And would it be fair to say that in the 24 course of your product development work while at 25 Wyeth, it was not focused on actually developing	74	1 litigation being finalized. So I played a major 2 role for them in that respect. 3 But I also helped in the development or 4 the change of focus of the product line so that it 5 would incorporate more of the kinds of products 6 that you see at GNC in today's market as opposed 7 to at the time that I started there. 8 Q. And what were those new kinds of 9 products that were being sold by GNC? 10 A. Well, I'll give you one example. The 11 product that was known as Cold-EEZE, which is a 12 zinc lozenge, very similar to the Zicam product, 13 was presented to me by the inventor. And he 14 wanted to market that product in a retail outlet. 15 And so I had to review his data to substantiate 16 the claims that he was making about his product. 17 GNC did not decide to take that product into their 18 portfolio, and so they had to market it elsewhere. 19 Q. Okay. And that would be an example of 20 what you were describing earlier as a homeopathic 21 medicine? 22 A. Yes. And they have a line of 23 homeopathic products, as well, tinctures and other 24 types of products along those lines that might 25 have been used as more of the cosmetic area. And	76

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20 (77 to 80)

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	77		79
1 so you see that today in a lot of products where 2 extracts of botanicals, et cetera, which are based 3 on homeopathic medicine may be found in commercial 4 products in today's market.		1 HEALON, which is hyaluronate acid. And it was 2 primarily used for injecting into the joints of 3 racehorses. And so my job was to do the blood 4 analysis work, the samples, in the laboratory that 5 I had at Rutgers University while I was a graduate 6 student.	
5 Q. Okay. And then your work at Pall 6 Biomedical Products, that looks like it was 7 focused more on the device side; is that correct?		7 Q. Okay. And then looking at the rest of 8 this page, your earlier consulting experience, 9 would it be fair to say that that also generally 10 relates to vitamins and other dietary supplements?	
8 A. Yes, Pall Biomedical Products was a very 9 interesting assignment for me. Dr. David Pall was 10 an expert in filtration systems. And the company 11 was looking to move into the area of application 12 in the biomedical field, so biomedical products or 13 medical devices, so to speak.		11 A. Yes, and primarily on a technical basis. 12 Again, as I said, many of these products -- excuse 13 me, many of these products were in need of 14 technical support, whether it was documentation or 15 support for claims that the company wanted to 16 make, as well as advisement relevant to regulatory 17 matters, and that's where I provided the help.	
14 And so the technology that Dr. Pall had 15 created in his filtration technology was to be 16 extended for applications primarily in a hospital, 17 either in filtration of blood and other fluids or 18 in the filtration of air particles, heat and 19 moisture exchanges that would be given to a 20 patient during the time that they were under 21 anesthesia.		18 Q. Okay. Thank you for that. 19 So is it correct that you do not have 20 any experience in the formulation or development 21 of oil-in-water nanoemulsions?	
22 Q. And then, lastly, looking at ICN 23 Pharmaceuticals, this looks like another 24 assignment focused on nutritional supplements?		22 MR. KREMEN: Objection to the form of 23 the question.	
25 A. Yes, that was. ICN Pharmaceutical	78	24 THE WITNESS: Well, let me just use the 25 example where in the vitamin industry, there are	80
1 wanted to branch out into the traditional area, 2 and so I was retained with the acquisition of what 3 was known as Faraday Laboratories, it no longer 4 exists, and brands that were primarily marketed to 5 allied health professionals. And the majority of 6 them would be in the chiropractic market.		1 products such as the fat soluble vitamins that 2 are -- utilize a delivery system that's known as a 3 micellar complex. And so you take a fat soluble 4 vitamin, and it's treated with surfactants or 5 whatever in order to make it more water soluble or 6 more miscible with the human body.	
7 Q. And then on the next page, it looks like 8 there's one other piece of employment listed --		7 BY MS. PETERSON:	
9 MR. KREMEN: Excuse me. The only thing 10 that's visible on the screen is the first page of 11 his résumé.		8 Q. Okay.	
12 MS. PETERSON: Okay. Let's look at 13 page 3, please. Can we turn to page 3.		9 A. So that's essentially what my experience 10 has been.	
14 BY MS. PETERSON:		11 Q. Okay. And just to confirm, those 12 products, those would be administered orally?	
15 Q. At the top here, it looks like this was 16 your first employment experience listed at 17 Pharmacia Laboratories. It looks like this was 18 following your undergraduate degree?		13 A. Yes.	
19 A. Actually, this was during the time of my 20 master's degree.		14 Q. Not through the nasal passages?	
21 Q. Okay.		15 A. No.	
22 A. So I had an undergraduate degree, but 23 this was a job that -- because Pharmacia was very 24 closely located near Rutgers University, and they		16 Q. Okay. And did you -- I mean, were you 17 aware of these fat soluble vitamins just as a 18 course of your work within the industry, or did 19 you actually develop and formulate any yourself?	
25 were interested in developing a product known as		20 A. No, they were developed by other people, 21 and I was -- I served as a scientific liaison to 22 give an explanation of the technology of these 23 other companies for the parent company that I was 24 employed by.	
		25 Q. Oh, okay. So you became aware of these	

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21 (81 to 84)

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	81		83
1 as a result of investigating them for potential 2 acquisition by your employer?		1 consulted for Matrixx was an oral zinc lozenge 2 product; correct?	
3 A. That's correct.		3 A. Actually, it was -- at the time the 4 portfolio included a nasal product, but I focused 5 primarily on the oral zinc product.	
4 Q. Okay. And so that would be the extent 5 of your experience that you said related to 6 oil-in-water nanoemulsions?		6 Q. And you don't have any experience in the 7 formulation or development of pharmaceutical 8 compositions that are intended to inhibit or 9 prevent infection caused by various bacteria?	
7 MR. KREMEN: Objection to the form of 8 the question.		10 MR. KREMEN: Objection to the form of 11 the question.	
9 THE WITNESS: I would say that my 10 experience with that was twofold. That's the 11 corporate side of it. But, also, on a personal 12 level, in order to document what's going on, this 13 is not a very simplistic concept for people in 14 marketing and people in corporate positions. So I 15 had to do a lot of investigating on my own about 16 the technology. So I had to learn the technology 17 myself in order to present it on behalf of that 18 company.		12 THE WITNESS: That experience, no. The 13 experience -- hands-on experience in development, 14 no.	
19 BY MS. PETERSON:		15 BY MS. PETERSON:	
20 Q. And what company was that presented to?		16 Q. And is it correct that you do not have 17 any experience in the formulation or development 18 of pharmaceutical compositions to inhibit or 19 prevent infection caused by viruses?	
21 A. Well, that was presented in several 22 companies. It was presented in ICN 23 pharmaceutical, but it was also presented at 24 General Nutrition Centers.		20 A. That's correct.	
25 Q. Okay. And then I assume you don't have		21 Q. Apart from your work on these two 22 litigation matters for Trutek, is it correct that 23 you do not have any experience in the formulation 24 or development of pharmaceutical compositions to 25 inhibit or prevent the nasal inhalation of any	
	82		84
1 any experience in the formulation or development 2 of oil-in-water nanoemulsions for nasal 3 administration; correct?		1 type of particulate matter into the nose?	
4 A. That's correct.		2 MR. KREMEN: Objection to the form of 3 the question.	
5 Q. Okay. And you do not have any 6 experience in the formulation or development of 7 oil-in-water nanoemulsions for use as a vaccine 8 adjuvant?		4 THE WITNESS: If I refer back to my 5 experience with Pall Corporation, with the 6 development of a medical device that was used for 7 the respiratory system, that's the only experience 8 that I can recall.	
9 A. That's correct.		9 BY MS. PETERSON:	
10 Q. And it sounds like you don't have any 11 experience in the formulation or development of 12 pharmaceutical compositions that are intended to 13 be administered nasally to humans?		10 Q. And that would be -- since it's a 11 medical device, that wouldn't be a composition 12 that's applied directly to a patient's skin; 13 correct?	
14 MR. KREMEN: Objection to the form of 15 the question.		14 A. No, it's applied directly over the nose 15 as a mask.	
16 THE WITNESS: Maybe you could rephrase 17 that for me.		16 Q. And I saw in your CV for Pall Biomedical 17 that -- is it correct that this work was related 18 to addressing issues of patients breathing cold 19 dry gas during surgery?	
18 BY MS. PETERSON:		20 A. That's correct.	
19 Q. You do not have any experience in the 20 formulation of pharmaceutical compositions that 21 are intended to be administered nasally to humans?		21 Q. Okay. Is it correct that you do not 22 have any experience in the formulation or 23 development of pharmaceutical products intended to 24 kill or inactivate bacteria or viruses within a 25 human nasal passage?	
22 A. My only exposure to that was with the 23 activities at Matrixx and Zicam because Zicam had 24 a product that was administered nasally.			
25 Q. Okay. But the product that you			

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22 (85 to 88)

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	85		87
1	MR. KREMEN: Objection to the form of	1	A. Yes, it relates to anything that I've
2	the question.	2	been employed. That's how I'm answering yes. So
3	THE WITNESS: I have no experience of	3	it's -- these are not situations where during the
4	development of those types of pharmaceuticals.	4	time that I was employed that I had experience
5	BY MS. PETERSON:	5	with that type of application.
6	Q. And you do not have any experience in	6	Q. Okay. Thank you.
7	the formulation or development of vaccines?	7	And I would assume then that in addition
8	A. That's correct.	8	to not having the experience in developing or
9	Q. And apart from your work in connection	9	formulating those types of products for those
10	10 with this matter, you do not have any experience	10	applications that you also wouldn't have any
11	11 in the formulation of pharmaceutical products	11	experience in testing those products either?
12	12 intended to capture and hold particulate matter	12	MR. KREMEN: Objection to the form of
13	13 within the nose or nasal passage?	13	the question.
14	MR. KREMEN: Objection to the form of	14	THE WITNESS: Testing the products would
15	15 the question.	15	not be part of my assignments in any of my
16	THE WITNESS: Just -- can you repeat	16	employment.
17	17 that question?	17	BY MS. PETERSON:
18	BY MS. PETERSON:	18	Q. Okay. And that would include any in
19	Q. So apart from the work that you're doing	19	19 vitro testing?
20	20 in connection with these litigations --	20	A. To my knowledge, yes.
21	A. Yes.	21	Q. Okay. So in vitro testing would not
22	Q. -- you do not have any experience in	22	have been part of your assignments for any of your
23	23 formulating or developing pharmaceutical products	23	work?
24	24 intended to capture and hold particulate matter	24	A. Correct.
25	25 within the nose or nasal passages?	25	Q. Okay. And in vivo testing in animals,
	86		88
1	A. Yes.	1	that also would not be part of your work
2	MR. KREMEN: Objection to the form of	2	experience?
3	3 the question.	3	A. My only experience in vivo would relate
4	4 THE WITNESS: Yes, just simply what I	4	to what I did at Pharmacia with the blood testing
5	5 referred to as far as the mask in Pall Biomedical.	5	and for my doctorate and my master's degree where
6	6 BY MS. PETERSON:	6	I did experimentation with animals.
7	7 Q. Okay. And that was a physical barrier,	7	Q. And what type of experimentation were
8	8 the mask; correct?	8	you doing as part of your thesis work?
9	A. Yes, that's a filtration device of a	9	A. Body compositional analysis of the
10	certain dimension to trap particles.	10	animals under specific types of dietary
11	11 Q. And is it correct that you do not have	11	restrictions as well as focusing on calcium
12	12 any experience in formulating or developing	12	nutriture as it relates to the development of
13	13 pharmaceutical products intended to capture and	13	osteoporosis under stressful conditions.
14	14 hold particulate matter within the nasal passage	14	Q. Okay. So that work also did not involve
15	15 by means of electrostatic attraction?	15	any testing or development or -- development of
16	16 MR. KREMEN: Objection to the form of	16	products intended to inhibit or prevent infection
17	17 the question.	17	of disease in those animals?
18	18 THE WITNESS: Yes.	18	A. No.
19	19 BY MS. PETERSON:	19	Q. Okay. Dr. Lemmo, do you consider
20	20 Q. And just to confirm, when you say yes,	20	yourself to have any particular expertise in
21	21 that means yes, that's correct, you do not have	21	patent law?
22	22 the experience?	22	A. No.
23	A. Yes, that's correct.	23	Q. And you do not have an economics degree?
24	24 Q. Okay. And the same is true for my other	24	A. Economics?
25	25 answers?	25	Q. Yeah.

Transcript of Edward A. Lemmo, Ph.D.

23 (89 to 92)

October 24, 2022

	89		91
1 A. No, no economics degree.		1 that.	
2 Q. You don't have an accounting degree?		2 Q. What about any experience with chemical	
3 A. No.		3 toxins?	
4 Q. And then with respect to your sales and		4 A. You're referring to xenobiotics.	
5 marketing experience from your prior employment,		5 Q. Sure. That would be an example.	
6 was that focused on making sure that the claims		6 A. Pollutants, pollutants and ways to boost	
7 made in those marketing or advertising materials		7 the immune system, but they would be primarily	
8 complied with applicable regulations?		8 with products that would enhance the natural	
9 MR. KREMEN: Objection to the form of		9 immunity of the body.	
10 the question.		10 Q. Okay.	
11 THE WITNESS: Well, let me explain. It		11 A. So in that respect, yes.	
12 did apply to the regulations, but it also applied		12 Q. And where did you do that work?	
13 to having adequate substantiation, scientific		13 A. Well, those products would be at GNC.	
14 substantiation for any of the claims associated		14 Q. Okay.	
15 with the products that were marketed so that		15 A. That -- we did a line of product called	
16 those -- the science evolves going forward, and so		16 cell support, and they were essentially	
17 claims will expire. And my function was to make		17 antioxidant products that were developed.	
18 certain that the claims were substantiated in		18 Q. And then what about do you have any	
19 light of any new developments.		19 experience in developing or formulating	
20 BY MS. PETERSON:		20 pharmaceutical products intended to inhibit	
21 Q. So the marketing and advertising work		21 infection caused by fungal spores?	
22 was focused on substantiating the claims that were		22 A. No.	
23 made in those materials with respect to the		23 Q. Okay.	
24 products?		24 MS. PETERSON: We've been going about an	
25 A. Yes, and also training the marketing and	90	25 hour. Do you want to take a short break at this	
1 salespeople regarding the product.	91		92
2 Q. Okay. And is it correct that you do not		1 point?	
3 have any experience in developing or formulating		2 MR. KREMEN: When do you want to -- do	
4 pharmaceutical products to prevent infection		3 you want to break for lunch at any point?	
5 caused by anthrax?		4 MS. PETERSON: Let's go off the record.	
6 A. Yes.		5 THE VIDEOGRAPHER: We're going off the	
7 Q. Yes, meaning you do not have that		6 record. The time is now 12:05 p.m.	
8 experience?		7 (Recess from the record.)	
9 A. I do not have that experience, no.		8 THE VIDEOGRAPHER: We're back on the	
10 Q. You also don't have any experience in		9 record. The time is now 12:48 p.m.	
11 developing or formulating pharmaceutical products		10 BY MS. PETERSON:	
12 to prevent infection or to inhibit infection		11 Q. Dr. Lemmo, did you have any	
13 caused by coronavirus?		12 conversations with anyone on either of the breaks	
14 A. I have no experience in that.		13 that we've taken today about the substance of your	
15 Q. Any experience with smallpox?		14 testimony that you've given?	
16 A. No experience in that.		15 A. No, I have not.	
17 Q. What about influenza?		16 Q. Now, Dr. Lemmo, we touched on this	
18 A. Same, no experience in that.		17 briefly, but you have provided opinions on what	
19 Q. What about avian flu?		18 you consider to be the appropriate level of skill	
20 A. No experience in that.		19 of a person of ordinary skill in the art in this	
21 Q. Swine flu?		20 matter; right?	
22 A. No experience in swine flu.		21 A. Correct.	
23 Q. Rhinovirus?		22 Q. And what do you consider to be the field	
24 A. Well, I've had rhinovirus. That's my		23 of the invention of the '802 patent?	
25 only experience, but no, not in the development of		24 A. Well, I see it really two ways. I see	
		25 it essentially as a medical device, but as an	

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Transcript of Edward A. Lemmo, Ph.D.

24 (93 to 96)

October 24, 2022

	93		95
<p>1 application which could be considered like a 2 cosmetic. But I do see it as a medical device. 3 Q. And you understand that the claims are 4 directed to a formulation? 5 A. Yes, that's correct. But the method of 6 delivering the formulation relates more in my 7 opinion to a medical device.</p> <p>8 Q. And how is the formulation to be 9 delivered?</p> <p>10 A. Well, as a medical device, since it's 11 applied to the skin and not in the nose, per se, 12 taken internally, I see it really as being 13 something that you're using that's applied to the 14 skin in the nasal passage area and possibly a 15 small distance into the nose, but not necessarily 16 something that is considered typically as a 17 pharmaceutical agent that you would be either 18 ingesting or somehow becoming more invasive.</p> <p>19 Q. So would you consider all pharmaceutical 20 products that are administered to the skin to be 21 devices?</p> <p>22 A. No. Some of them are topical agents 23 that are specific for the treatment of skin 24 conditions.</p> <p>25 Q. And topical -- drugs that are delivered</p>		<p>1 BY MS. PETERSON: 2 Q. But the object of the invention is not 3 to moisturize the skin; is it? 4 A. No, it's not. 5 Q. The object of the invention is to 6 inhibit infection by microorganisms in an 7 individual?</p> <p>8 A. I think it's to inhibit particle flow 9 into the respiratory system. It doesn't restrict 10 itself to microorganisms.</p> <p>11 Q. Sure. 12 So microorganisms, though, are 13 encompassed by the claims; correct?</p> <p>14 A. Yes, anything that would be in the 15 airflow stream that would be entering the 16 respiratory system, according to the way I read 17 it, would be included in that, yes.</p> <p>18 Q. So that would include microorganisms; 19 right?</p> <p>20 A. Pollen, microorganisms, bacteria, 21 viruses, animal dander, a number of items that 22 potentially are in the airstream. There could be 23 even pollutants, as I mentioned before, with the 24 xenobiotics, chemical entity, smoke can all be in 25 your airstream, depending on your environment.</p>	
<p>1 topically can also be used for systemic treatment, 2 as well; right?</p> <p>3 A. Yes, that's correct. Both in humans as 4 well as in animals.</p> <p>5 Q. And the formulation that's described in 6 the '802 patent, it doesn't require any special 7 device for a person to apply it to their skin 8 around the nasal passages; correct?</p> <p>9 A. That's correct. You could apply it with 10 your finger.</p> <p>11 Q. So if it's a gel or a cream, it would 12 just be applied directly?</p> <p>13 A. That's correct.</p> <p>14 Q. And you also mentioned that it was 15 similar to a cosmetic, but you understand that the 16 claims also require, I guess what we would call, 17 active ingredients to prevent or inhibit 18 infection; correct?</p> <p>19 MR. KREMEN: Objection to the form of 20 the question.</p> <p>21 THE WITNESS: The composition contains 22 ingredients that are moisturizing to the skin. 23 They may be emollients there that are moisturizing 24 to the skin, and that's why I would consider that 25 composition similar to a cosmetic.</p>	94	<p>1 Q. And cosmetics aren't typically used to 2 treat or inhibit infection caused by 3 microorganisms or bacteria or viruses; correct?</p> <p>4 A. Cosmetics are -- can you just repeat 5 that? You said are --</p> <p>6 Q. Cosmetic products are not typically used 7 to treat or inhibit infection caused by 8 microorganisms such as bacteria or viruses that 9 enter the respiratory system?</p> <p>10 A. Yes. Yes, I would consider cosmetics to 11 be, as their name implies, either something that 12 you're applying to the skin to improve the 13 appearance or the condition of the skin. 14 Essentially it's different.</p> <p>15 Q. Okay. Now, I -- okay. So going back to 16 your opinions on what you believe to be the person 17 of ordinary skill in the art, has your opinion 18 changed since you provided it in your reports?</p> <p>19 A. Based upon what I've read, as far as its 20 definition, and since I'm not legally trained on 21 how it's used legally, I have to base my opinion 22 on what I read. But I have not changed my opinion 23 on what you consider to be a person of ordinary 24 skill in the art.</p> <p>25 Q. Okay. No, I just want to understand if</p>	96

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Transcript of Edward A. Lemmo, Ph.D.

25 (97 to 100)

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	97		99
1 your opinion is still the same as how it's 2 explained in your reports?		1 the Matrixx matter and in this matter. 2 Did I understand that correctly?	
3 A. Absolutely, I understand that. Yes, 4 it's the same.		3 A. Yes, that's correct.	
5 Q. Okay. And you said that your opinion 6 was based on what you read. What materials did 7 you read that informed your opinion?		4 Q. Okay. I just want to make sure I didn't 5 miss anything. You did not provide any opinions 6 in this matter directed to infringement using 7 Dr. Amiji's standard of a person of ordinary skill 8 in the art?	
8 A. Well, essentially, I went online to see 9 what the definition is from a patent standpoint. 10 There are references to both a person of ordinary 11 skill, as well as a person of extraordinary skill. 12 So I tried to educate myself before I wrote 13 anything regarding an opinion on what I've read.		9 MR. KREMEN: Objection to the form of 10 the question.	
14 Q. Okay. And do you -- I don't think those 15 online definitions were cited in your report. Do 16 you recall what references or materials you viewed 17 online to obtain this information?		11 BY MS. PETERSON:	
18 A. Yeah, quite honestly, at this point I 19 don't remember when I did that.		12 Q. Let me rephrase.	
20 Q. Okay. And you understand that Dr. Amiji 21 has offered a differing opinion of the level of 22 skill?		13 So your opinions that you provided in 14 this matter as reflected in your expert reports 15 and in your declaration, you applied your 16 understanding of the level of a person of ordinary 17 skill in the art; correct?	
23 A. Yes, I read his reports, and I do 24 respect his -- you know, his experience and his 25 comments, but I differ.		18 A. That's correct.	
1 Q. Yeah, I understand.	98	19 Q. Did you provide any alternative or 20 different opinions on those same issues but 21 instead using Dr. Amiji's definition?	
2 Do you consider yourself to be a person 3 of ordinary skill in the art directed to the '802 4 patent under your definition?		22 MR. KREMEN: Objection to the form of 23 the question.	
5 A. Considering everything that I've read 6 over time, I would have to exclude myself as a 7 person of ordinary skill and more towards the 8 person of extraordinary skill, since I've spent a 9 good deal of time, not only in this particular 10 case but in the previous case with Matrixx, trying 11 to understand and grasp the concept.		24 THE WITNESS: No.	
12 Q. So that would be based on your research 13 and the work that you did in forming your opinions 14 in both the Matrixx litigation matter as well this 15 present litigation matter?		25	
16 A. Yes, and I --	100		
17 MR. KREMEN: Objection to the form of 18 the question.		1 BY MS. PETERSON:	
19 THE WITNESS: You might want to repeat 20 that question as far as I got into -- there was an 21 interference, I'm sorry.		2 Q. Okay. Let's pull up your responsive 3 report.	
22 BY MS. PETERSON:		4 MS. PETERSON: This is Exhibit 14. And 5 we'll go to page 2 of the report.	
23 Q. I think you said it was -- your prior 24 comment that it was based on the research and the 25 work that you've done in forming your opinions in		6 And could we go down one page.	

Transcript of Edward A. Lemmo, Ph.D.

26 (101 to 104)

October 24, 2022

	101		103
1 A. Yes, that's correct.		1 their level of -- their level of sophistication or	
2 Q. And so, in your opinion, it would be a		2 level of education that they need in order to	
3 technician?		3 carry out that function.	
4 A. A technician would qualify, yes.		4 Q. Okay. Did Mr. Kremen or any other	
5 Q. Okay. And I think if we look maybe four		5 counsel for Trutek provide you with any	
6 sentences down or so on the page, you say, "A		6 explanation or framework for how to determine the	
7 PHOSITA is primarily a technician in his chosen		7 level of skill for a POSITA as it relates to the	
8 field" --		8 '802 patent?	
9 A. Yes.		9 A. I've had discussion with Mr. Kremen	
10 Q. -- "and his skills are those ordinarily		10 regarding the person of ordinary skill from the	
11 associated with such a technician"; correct?		11 legal standpoint just to see if, in fact, in	
12 A. That's correct.		12 reviewing the material, you know, if I was on the	
13 Q. Okay.		13 right track, I was explaining it correctly.	
14 MS. PETERSON: If we could scroll down a		14 Q. Okay. And the -- those legal stand --	
15 little bit more to the bottom of this page.		15 let me start over.	
16 BY MS. PETERSON:		16 The legal framework or guidelines or	
17 Q. The last paragraph, it looks like you're		17 framework that Mr. Kremen provided to you, you	
18 drawing on your experience as a college professor.		18 don't have that explained or set out in your	
19 And it looks like teaching both students who are		19 report; correct?	
20 non-majors as well as students who are majoring in			
21 that particular discipline; correct?			
22 A. That's correct.		20 A. That's correct.	
23 Q. And is it your opinion that the POSITA		21 Q. Okay. Now, in the laboratory setting,	
24 for the '802 patent would be someone who took		22 what is your understanding of the difference	
25 general courses in the relevant subject matter but		23 between a technician and, say, you know, someone	
	102	24 with more experience who's running the lab or	
1 did not major or focus on that field at any level?		25 supervising the research?	
2 A. That's correct.			
3 Q. So all of this discussion that we just			
4 went through right now, that would be your general			
5 understanding of what a person of ordinary skill			
6 in the art should be?			
7 MR. KREMEN: Objection to form.			
8 THE WITNESS: The -- could you just			
9 repeat that question for me, I'm sorry?			
10 BY MS. PETERSON:			
11 Q. Yeah.			
12 So all of those statements that we just			
13 went through, those reflect your general			
14 understanding of what a person of ordinary skill			
15 in the art should be?			
16 A. Yes, the qualifications that I would			
17 consider.			
18 Q. Okay. And the basis for that			
19 understanding is in part based on what you			
20 reviewed online about the standard?			
21 A. My readings and I think from my			
22 experience in product development as far as the			
23 basic concepts that are employed by in getting a			
24 product from concept to finished product, the			
25 people who would be involved in that process and			
	103		104
1 MR. KREMEN: Objection to the form of		1 MR. KREMEN: Objection to the form of	
2 the question.		2 the question.	
3 THE WITNESS: You might have to rephrase		3 THE WITNESS: You might have to rephrase	
4 that for me.		4 that for me.	
5 BY MS. PETERSON:		5 BY MS. PETERSON:	
6 Q. Well, you've said that you think the		6 Q. Well, you've said that you think the	
7 appropriate level of skill is that of a		7 appropriate level of skill is that of a	
8 technician, and so I just want to understand, you		8 technician, and so I just want to understand, you	
9 know, what is a technician? Like what are their		9 know, what is a technician? Like what are their	
10 basic qualifications, especially relative to other		10 basic qualifications, especially relative to other	
11 people with more experience?		11 people with more experience?	
12 A. Okay. Based on my professional		12 A. Okay. Based on my professional	
13 experience in the corporate setting, the		13 experience in the corporate setting, the	
14 laboratory was headed or directed by a person who		14 laboratory was headed or directed by a person who	
15 would be a Ph.D. level scientist. That person		15 would be a Ph.D. level scientist. That person	
16 would be my peer as a Ph.D. scientist who is in		16 would be my peer as a Ph.D. scientist who is in	
17 charge of the development product -- the		17 charge of the development product -- the	
18 development of products. But carrying out		18 development of products. But carrying out	
19 responsibility of getting the concept to the steps		19 responsibility of getting the concept to the steps	
20 necessary to either quantify or quality of the		20 necessary to either quantify or quality of the	
21 materials used in the product would be individuals		21 materials used in the product would be individuals	
22 who would be at a lower level.		22 who would be at a lower level.	
23 On the manufacturing side, the person		23 On the manufacturing side, the person	
24 who would be formulating the product, making the		24 who would be formulating the product, making the	
25 physical product from the concept that I designed,		25 physical product from the concept that I designed,	

Transcript of Edward A. Lemmo, Ph.D.

27 (105 to 108)

October 24, 2022

	105		107
1 developed, created, whatever terminology you wish 2 to use, that individual may not have an advanced 3 degree but has the experience or capacity to carry 4 it out from the concept that I explain to the 5 finished product that the consumer would receive.		1 MR. KREMEN: Objection to form. 2 THE WITNESS: The way I understand that, 3 for what you're asking me, is that a person who's 4 carrying out an experiment could carry out that 5 experiment once they've had the experience as a 6 reason -- not necessarily formal education 7 experience. I could go back to also my statement 8 regarding the student.	
6 Q. Okay. So the technician then that 7 you're referring to, that would be someone who on 8 the manufacturing side has the experience 9 necessary to carry out the instructions for how to 10 make the product, how to formulate the product; 11 right?		9 In my experience in teaching students 10 laboratory procedure, the students should be able 11 to, after the instruction was given by me, carry 12 out those laboratory experiments, even though that 13 student may not even have a degree.	
12 A. Yes. For example, if a product has to 13 be produced in a specific dosage form -- tablet, 14 capsule, liquid, whatever -- and there is 15 equipment involved, that technician would know 16 about binder, fillers, other agents that might be 17 necessary to get the concept of the active 18 ingredient that I want to create in this product 19 into a form that maintains its stability and in a 20 form that will be easy and understandable by the 21 end user.		14 BY MS. PETERSON: 15 Q. Okay. So as long as the required 16 instruction is provided to the student or the 17 technician, they should be able to carry out that 18 experimentation?	
22 Q. And so the technician would then 23 primarily be someone who is following directions 24 provided by the more experienced supervisor? 25 A. Yes, or from me, as far as the		19 MR. KREMEN: Objection to form. 20 THE WITNESS: They should recognize 21 certain elements of what would be necessary to 22 carry out the procedure. 23 BY MS. PETERSON: 24 Q. Would a technician or a non-major 25 student typically be expected to design their own	
	106		108
1 appearance of the product that I'm looking to 2 create, whatever the case may be. Or that person 3 might, in fact, as you say, go to a supervisor and 4 get advice from that individual from a more 5 technical standpoint, yes. 6 Q. Would a technician typically be 7 designing their own experiments, or would they be 8 looking to the supervisor for input on that type 9 of work? 10 A. I think you've got two things working 11 here. The technician could carry out the 12 experimentation because it's almost like a 13 cookbook for the experimentation. It doesn't 14 really require a person -- if you've been doing 15 this, you pretty much know how to do it from that 16 standpoint. From the manufacturing standpoint, I 17 think it's also the technician who could carry it 18 out to get it through that process so that you 19 have uniformity at the end. 20 Q. Okay. So on the experimentation piece 21 then, the technician is able to conduct the 22 experiment because he or she either knows what 23 experiment to conduct and they've done it before 24 or they're provided instructions that they're able 25 to follow; is that right?	1 experiment to test a particular feature of a 2 product if they haven't been given instructions or 3 haven't had the experience in testing for that 4 feature? 5 A. I could only address my own experience 6 in that capacity. When I was a college student, 7 one of the courses that I had to take was design 8 of experiment. And so without an advanced degree, 9 I essentially had to design an experiment. And of 10 course it was presented to the professor to see 11 whether or not I did it correctly. But the answer 12 is yes, you can definitely design experiments. 13 You can do things or carry out procedures 14 accordingly, even though the person may not have 15 an advanced degree. 16 And just as a follow-up to that, in 17 reading some of the comments by Dr. Amiji on a 18 person of ordinary skill, he does comment in a 19 similar way to me in his report on invalidity, and 20 he clearly stated that a person of ordinary skill 21 in the art would know about things like viscosity 22 and relative to the term of "adequate 23 impermeability." 24 So I think there's definitely somewhat 25 of an understanding here. You know, this term --		

Transcript of Edward A. Lemmo, Ph.D.

28 (109 to 112)

October 24, 2022

	109		111
1 this term is something that needs to be 2 interpreted so we can have some agreements 3 regarding that. And I would refer you essentially 4 to his report on invalidity. I think it was 5 page 51, as I remember, because I remember reading 6 that.		1 knowledge and understanding of the prior art would 2 not necessarily inform the POSA about how to make 3 and use the claimed invention; right?	
7 Q. Okay. Would a student taking a certain 8 course outside of his or her major typically be 9 expected to be familiar with scientific literature 10 in that field outside of what is taught in the 11 course?		4 MR. KREMEN: Objection to the form of 5 the question. If you understand it.	
12 A. That's really subject to the professor 13 whether -- in my courses, for example, I always 14 provided students with opportunity to visit the 15 library and do independent study, whether they 16 were majors or not. So, you know, I feel that 17 that's part of the learning process to learn on 18 your own as opposed to just reiterating what the 19 professor has taught. It creates for you an 20 independent thinker.		6 THE WITNESS: I don't understand the 7 question. You might want to clarify that for me.	
21 Q. And going back to the laboratory or the 22 manufacturing setting, if a technician were to run 23 into a problem or an issue in carrying out the 24 concept or the instructions, would they typically 25 look to that more experienced supervisor for		8 BY MS. PETERSON:	
1 advice or guidance on how to address the issue? 2 A. I would encourage that. If the 3 technician comes back to me, for example, with 4 choices of a component that I would like to use in 5 the product and suggests to me that this would 6 work better but it's in the same category, I would 7 give that person the opportunity to go ahead and 8 do that, go forward and use that as a substitute. 9 And I've done that in my experience.	110	9 Q. Well, I guess another way to look at it 10 is if the instructions or explanation for how to 11 make and use the claimed invention are not in the 12 prior art, then they would have to be provided 13 directly in the patent; correct?	
10 Q. Okay. I think my question was a little 11 bit different, directed to a circumstance where a 12 technician runs into a problem, like the 13 instructions that were provided aren't working. 14 What would the technician do next? Would they go 15 to the supervisor for --		14 A. I think that's a matter of patent law. 15 So I would agree. But that should not preclude	
16 A. Yes.		16 THE WITNESS: I think that's a matter of patent law. 17 So I would agree. But that should not preclude	112
17 Q. -- input on how to correct that problem?		18 A. Yes.	
18 A. Yes, I would expect them to.		19 Q. You can read and understand what is 20 explained in the patent.	
19 Q. Now, I think you also explained that it 20 is your understanding that the POSA also knows of 21 and understands all of the prior art in his field 22 of endeavor; correct?		21 A. Yes. Is it also your opinion that the 22 person of ordinary skill in the art must 23 necessarily be able to make and use the claimed 24 invention?	
23 A. Yes.		25 A. Again, I'm not clear on making and using the claimed invention. Maybe can you just give me a clarification on that again, I'm sorry?	
24 Q. Okay. So if a claimed invention is new 25 and not described in the prior art, then that		26 Q. Sure. Give me one second because I think this is --	
		27 A. Sure.	
		28 Q. -- mostly a direct quote from your report.	
		29 A. Sure. Yeah, if you identify where it is, I can read the statement again. This way I'm clearer.	
		30 Q. Okay. Let's take a look at -- oh, we're on the right page, page 3.	

Transcript of Edward A. Lemmo, Ph.D.

29 (113 to 116)

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	113		115
1 MS. PETERSON: Can we scroll up to the 2 top? 3 BY MS. PETERSON: 4 Q. The second full sentence, you state, "He 5 must have sufficient experience in his art so as 6 to become competent and understand and interpret 7 the prior art related to a patent so that he can 8 make and use the invention described and claimed 9 in the patent." 10 A. Yes. 11 Q. So that's your opinion? 12 A. Yes, it is. 13 Q. Okay. 14 A. Yeah. Yeah, I wasn't sure what you were 15 referring to. Thank you for identifying it. 16 Q. I was paraphrasing. I should have 17 pointed directly to the report, I apologize. 18 A. Not a -- no need to. 19 Q. But just to understand, so it is your 20 opinion that a person of skill in the art will 21 necessarily be able to make and use the claimed 22 invention as described in the patent? 23 A. Yes. 24 Q. Now, all of this is in contrast, I 25 think, to what you described as an extraordinary		1 providing your explanation as to the specific 2 level of skill possessed by a person of ordinary 3 skill in the art for the '802 patent; correct? 4 A. Yes, that's correct. 5 Q. And so specifically, it would be the 6 level of skill of that of a chemical or a 7 pharmaceutical formulator? 8 A. Yes. And as I said previously, it could 9 be an individual who is not classified in that 10 terminology or in that manner but could be an 11 individual who, again, has read extensively on the 12 subject matter. 13 Q. Okay. And then you set out two 14 qualifications for the person of ordinary skill in 15 the art; correct? 16 A. Yes, I have two related but separate 17 qualifications, yes. 18 Q. Okay. And the first qualification, is 19 that after reading the '802 patent, he should be 20 able to create the formulations described in the 21 patent; right? 22 A. Yes, that's stated. 23 Q. And then the second qualification is 24 that the person of skill in the art must be 25 positioned in time just prior to the effective	
	114		116
1 skilled person? 2 A. Yes. 3 Q. And that would be someone who has an 4 advanced degree? 5 A. Yes, and I think who qualifies as a 6 person of advanced skill in the area. There are 7 many individuals who I respect and read their 8 scientific views on things, and those are the 9 people that I consider to be extraordinary. 10 Q. Okay. And that extraordinarily skilled 11 person could also be a student who is majoring in 12 that particular subject matter? 13 A. Yes, I think that a person who is 14 extraordinary in their skill has some fundamental 15 knowledge of concepts. In this particular case, 16 some of these concepts are essentially taught to 17 us in a high school setting or in an undergraduate 18 setting. And then based on those skills or that 19 knowledge, that person can proceed to reach an 20 advanced degree but always hold on to those basic 21 skills. 22 Q. Okay. Let's move forward two pages to 23 page 5. 24 A. Okay. 25 Q. And I think here on page 5, now you're	1 filing date of the '802 patent; right? 2 A. Yes. 3 Q. So that's referring to the time period 4 that we're looking at as opposed to any particular 5 qualifications of the person of ordinary skill in 6 the art? 7 A. Yes. 8 Q. Okay. 9 A. And my thought -- you know, that's just 10 a reflection of my thought process at the time. 11 So at the time we have to go back to that year, or 12 whatever year we're looking at, what was the level 13 of knowledge within the scientific community 14 related to the subject. 15 Q. Okay. And then you provide some 16 additional explanation on this same page 17 indicating that the person of ordinary skill in 18 the art would have the skill and experience to 19 duplicate the formulations listed in the '802 20 patent; right? 21 A. Yes. 22 Q. Okay. And then looking on the next 23 page? 24 A. Page 6? 25 Q. Yep.		

Transcript of Edward A. Lemmo, Ph.D.

30 (117 to 120)

October 24, 2022

<p>1 A. Yes.</p> <p>2 Q. The very last sentence, you explain, I 3 think what you identified, as your key requirement 4 for the person of ordinary skill in the art; is 5 that right?</p> <p>6 A. Yes.</p> <p>7 Q. And that would be the required 8 experience --</p> <p>9 MR. KREMEN: Where are we?</p> <p>10 THE WITNESS: Page 6. Page 6, first 11 paragraph.</p> <p>12 MS. PETERSON: There you go.</p> <p>13 BY MS. PETERSON:</p> <p>14 Q. Okay. So the key requirement, in your 15 opinion, is that the person of ordinary skill in 16 the art is -- has acquired experience -- or it is 17 the acquired experience necessary to create a wide 18 variety of formulations from the class of 19 ingredients disclosed in the '802 patent; right?</p> <p>20 A. Yes, that's what I described earlier, 21 where if there are options that as stated, if you 22 remember our previous conversation relative to the 23 '802 patent with the various tables of 24 ingredients, but they identify categories, and so 25 that person of ordinary skill in the art would be</p>	<p>117</p> <p>1 Okay. So looking at Claim 1, it starts 2 out with what we call a preamble. That would be 3 the opening phrase.</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And it refers to "A method for 7 electrostatically inhibiting harmful particulate 8 matter from infecting an individual through nasal 9 inhalation wherein a formulation is applied to 10 skin or tissue of nasal passages of the individual 11 in a thin film"; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. And then following that there are 14 three other claim elements, A, B, and C; right?</p> <p>15 A. Yes.</p> <p>16 Q. And I think those are what you refer to 17 respectively as capturing, holding, and killing; 18 is that right?</p> <p>19 A. Yes, it's a -- forgive me for doing 20 that, but it's how I try to convey messages 21 sometimes to an audience that may not be 22 scientifically directed. So it's a habit.</p> <p>23 Q. Okay. And then looking at Claim 2, 24 Claim 2 is very similar to Claim 1 except that it 25 recites a formulation instead of a method; right?</p>
<p>1 able to decipher or understand the various options 2 that they have available to them as recited in the 3 patent.</p> <p>4 Q. Okay.</p> <p>5 MS. PETERSON: We can pull that exhibit 6 down.</p> <p>7 BY MS. PETERSON:</p> <p>8 Q. And let's go back and take a look at 9 Exhibit 2. This is the '802 patent.</p> <p>10 A. I think I have a copy instead of an 11 electronic copy here. It's easier for me to read.</p> <p>12 Q. Yep, that's fine.</p> <p>13 A. My eyesight in my advanced years is -- 14 it's easier to look at it here. I have it.</p> <p>15 Q. Okay. So you've reviewed the '802 16 patent in its entirety; right?</p> <p>17 A. Yes.</p> <p>18 Q. The specification as well as all of the 19 claims?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And let's take a look at Claim 1.</p> <p>22 MR. KREMEN: Can we do that on the 23 screen?</p> <p>24 BY MS. PETERSON:</p> <p>25 Q. So it will be page 6 of the PDF.</p>	<p>118</p> <p>1 A. That's correct.</p> <p>2 Q. Okay. And in addition to those elements 3 of Claim 1 that we just walked through, Claim 2 4 also adds the express requirement that the 5 formulation contains at least one cationic agent 6 and at least one biocidic agent; right?</p> <p>7 A. That's correct.</p> <p>8 Q. And then if we look at Claims 6 and 7, 9 which are at the bottom of the page, those are 10 dependent claims where the cationic agent and the 11 biocidic agent specifically are benzalkonium 12 chloride; right?</p> <p>13 A. That's correct.</p> <p>14 Q. Or in the case of Claim 7, the biocidic 15 agent can be benzalkonium chloride or Lysine HCL?</p> <p>16 A. Hydrochloride, correct.</p> <p>17 Q. Okay. Now, you understand that because 18 these claims use the word "comprising" that the 19 formulations can also include additional 20 ingredients; right?</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p> <p>23 MR. KREMEN: Calls for a legal 24 conclusion.</p> <p>25</p>

Transcript of Edward A. Lemmo, Ph.D.

31 (121 to 124)

October 24, 2022

	121		123
1 BY MS. PETERSON:		1 A. That's correct.	
2 Q. And you would also agree that Claims 1		2 Q. It must be able to electrostatically	
3 and 2, they do not just recite a formulation		3 inhibit harmful particulate matter from infecting	
4 having certain ingredients; right?		4 an individual through nasal inhalation?	
5 MR. KREMEN: Objection to the form of		5 A. That's correct.	
6 the question.		6 Q. And the formulation must also be applied	
7 THE WITNESS: Well, Claim 1 is a method.		7 to the skin or tissue of nasal passages in a thin	
8 BY MS. PETERSON:		8 film?	
9 Q. Yeah, it's a method of using a		9 A. Yes, that's correct.	
10 formulation; right?		10 Q. And Claim 2 also requires that the thin	
11 A. Yes, you said Claim 1 and 2.		11 film applied or formed upon application of the	
12 Q. Okay. So -- but Claim 1 does refer to a		12 formulation must electrostatically attract	
13 method of using the formulation; right?		13 particulate matter to the thin film?	
14 A. Yes.		14 A. That's correct.	
15 Q. Okay. And you agree that Claims 1 and 2		15 Q. And the claims also require that the	
16 do not just recite a formulation having certain		16 thin film must hold the particulate matter in	
17 ingredients or a method of using a formulation		17 place?	
18 having certain ingredients; right?		18 A. Correct.	
19 MR. KREMEN: Objection to the form.		19 Q. And the formulation must also provide	
20 THE WITNESS: Your question is a little		20 adequate impermeability to the thin film?	
21 bit confusing to me if you could restate it.		21 A. Correct.	
22 BY MS. PETERSON:		22 Q. Okay. So those are all functions that	
23 Q. Okay. Let's look at just Claim 2.		23 the claim requires the formulation to provide;	
24 Would you agree that Claim 2 does not		24 right?	
25 just recite a formulation having certain		25 A. Correct. Yes.	
	122		124
1 categories of ingredients?		1 Q. And those same functions are recited in	
2 MR. KREMEN: Objection to form.		2 Claim 1, as well; right?	
3 THE WITNESS: In Claim 2, if we look at		3 A. That's correct.	
4 that information, it's -- it doesn't really spell		4 Q. Okay. Now, I think we all understand	
5 out exactly what you're saying, I think. I may be		5 this, but is it your understanding that all	
6 a little bit confused as far as how you're		6 cationic agents will have a positive charge?	
7 interpreting that claim.		7 A. Yes.	
8 BY MS. PETERSON:		8 Q. Okay. And the functions recited in the	
9 Q. Okay. Well, it doesn't read a		9 claims of electrostatically inhibiting and	
10 formulation containing a biocidic agent and a		10 electrostatically attracting, those are the	
11 cationic agent period. There are other elements		11 results of the positive charge of a cationic	
12 to the claim; right?		12 agent; right?	
13 A. Yes.		13 MR. KREMEN: Objection to the form.	
14 Q. So the formulation that is described in		14 THE WITNESS: Of the formulation.	
15 Claim 2 also has another -- has a number of other		15 BY MS. PETERSON:	
16 elements or functions that the formulation will		16 Q. So it's the positive charge of the	
17 perform; right?		17 formulation?	
18 A. Yes, and they're recited in the tables		18 A. Yes.	
19 in the body of the patent.		19 Q. Okay. So you understand that even if a	
20 Q. The ingredients are recited in the		20 particular formulation includes a cationic agent	
21 tables?		21 with a positive charge, that other components or	
22 A. Yes, that's correct.		22 ingredients in the formulation could impact the	
23 Q. Okay. But looking at Claim 2, Claim 2		23 overall charge of the formulation?	
24 recites specific functions that the formulation		24 MR. KREMEN: Objection to the form of	
25 should be able to perform; right?		25 the question.	

Transcript of Edward A. Lemmo, Ph.D.

32 (125 to 128)

October 24, 2022

	125		127
1 THE WITNESS: You may want to clarify 2 that. 3 BY MS. PETERSON: 4 Q. So the formulation we're talking about 5 here, it doesn't just exist of only a cationic 6 agent; right? 7 A. That's correct. 8 Q. Okay. And you understand that other 9 ingredients in the formulation could impact the 10 overall charge of the formulation; right?		1 Q. Okay. The patent also describes a 2 number of biological or chemical elements, toxins, 3 and irritants, as well, that can be addressed by 4 the claimed invention; right? 5 A. Yes. Yes, that's correct. 6 Q. And the '802 patent also describes 7 preventing or inhibiting the infection of airborne 8 microorganisms? 9 A. I think the correct term here is 10 "inhibiting" them. 11 Q. Okay. So the '802 describes airborne -- 12 or the '802 patent describes airborne 13 microorganisms as another example of harmful 14 particulate matter that the claimed invention is 15 intended to inhibit the infection of; right? 16 A. If it's an infecting agent, yes. 17 Q. Also airborne fungal spores? 18 A. Any agent that would be in the airstream 19 at a concentration when a person is coming in 20 contact with it with a concentration of those 21 particles are irritants, negatively charged items, 22 they would all be classified as those that would 23 come in contact with the formulation and be 24 rendered, held onto as it states in Claim 1, 25 Section B. So that holding aspect is a very	
11 MR. KREMEN: Objection to form. 12 THE WITNESS: Other ingredients are in 13 the formula and may contribute cationic charge. 14 BY MS. PETERSON: 15 Q. And they could also make the charge 16 lower, as well; right? 17 A. If the ingredient is neutralizing the 18 cation. 19 Q. Okay. Yeah. So there could be 20 ingredients included in a formulation that could 21 neutralize the charge of the cationic agent 22 altogether; right? 23 A. It depends on the amount that's present 24 in the formula. 25 Q. Okay. And would you also agree that the	126		128
1 pH of a formulation could impact the charge of the 2 formulation? 3 A. Yes. 4 Q. And the pH of the environment where the 5 formulation is applied could also impact the 6 surface charge; right? 7 A. Yes. 8 Q. Okay. So we also understand from 9 Claims 1 and 2 that the formulation is being used 10 in a manner to inhibit harmful particulate matter 11 from infecting an individual through nasal 12 inhalation; correct? 13 A. That's correct. 14 Q. And the '802 patent provides examples of 15 those harmful particulate matters; right? 16 A. That's correct. 17 Q. And it includes things like anthrax, 18 spores, various viruses like coronavirus, smallpox 19 virus, influenza, avian flu, swine flu, and 20 rhinovirus? 21 A. I would classify all of those as 22 negatively charged particles. 23 Q. Sure. But the patent describes a wide 24 variety of different viruses. 25 A. Yes.		1 important aspect of what's claimed here. 2 Q. Okay. And still looking at the types of 3 harmful particulate matters identified by the '802 4 patent, there's also a group of bacterial diseases 5 that are identified for which infection can be 6 inhibited; right? 7 A. Yes, absolutely. 8 Q. And that would include the bacteria that 9 are responsible for causing whooping cough, 10 meningitis, diphtheria, pneumonia, tuberculosis, 11 and anthrax? 12 A. Yeah, any of the bacteria that would 13 have a membrane structure that you've recited 14 would be affected by virtue of the cationic nature 15 of the formulation. 16 Q. Oh, okay. So, in other words, the -- 17 it's that membrane structure -- that membrane 18 structure would be disrupted by the cationic agent 19 or the biocidic agent? 20 A. That's correct. 21 Q. Okay. And as long as the harmful 22 particulate matter is negatively charged, then the 23 claimed invention will capture and hold those 24 harmful particulate matters, as well? 25 MR. KREMEN: Object to form.	

Transcript of Edward A. Lemmo, Ph.D.

33 (129 to 132)

October 24, 2022

	129		131
1 Which claim are you talking about, 1 or 2 2?		1 decades; right? 2 A. Oh, I believe since the 1930s from the 3 literature that I've read on the subject, yes.	
3 MS. PETERSON: Both. 4 MR. KREMEN: Okay. You can answer.		4 Q. Okay. Let's take a look at Column 4 of 5 the patent.	
5 THE WITNESS: Yes, in 1, we're talking 6 about attracting because of the charge difference 7 and then holding it and essentially reaching that 8 point of adequate impermeability where the product 9 then -- or the bacteria, if that's what we're 10 referring to -- becomes inactivated by means of 11 the agents that are present. And that 12 inactivation is essentially going to apply to 13 those negatively charged particles that are in the 14 airstream that could potentially create a problem 15 for the individual.		6 MR. KREMEN: You have to scroll up. 7 Keep going. One more.	
16 So it's just a matter of looking at it 17 from a particulate matter standpoint. And that's 18 why I used the expression earlier that I viewed it 19 more as a medical device that happens to employ a 20 formulation. If I've made myself clear.		8 MS. PETERSON: Yeah, so down at the 9 bottom of that page. If we can go all the way 10 down to the bottom.	
21 BY MS. PETERSON:		11 BY MS. PETERSON:	
22 Q. I'm not sure that that was clear, but 23 that's okay. We can move on.		12 Q. Do you see at the very bottom, starting 13 at line 65, the '802 patent describes a 14 formulation of the invention comprises and then 15 there's a list of ingredients, including water, at 16 least one quaternary thickener --	
24 A. Okay.		17 MS. PETERSON: And then if we scroll 18 down --	
25 Q. So benzalkonium chloride, you're		19 BY MS. PETERSON:	
	130		
1 familiar with that agent; right?		20 Q. -- a preservative, a conditioner, an 21 emulsifier, a biocidic agent, and a neutralizing 22 agent added to adjust and achieve a pH in the 23 range of 5.0 to 6.8?	
2 A. Yes. Yes, I am.		24 Do you see that?	
3 Q. And when you used as a biocide, it works 4 by disrupting or breaking up the cell membrane of 5 an organism; right?		25 A. Yes.	
6 A. That's correct. That's correct.			
7 Q. So it won't have the same effect on 8 something where the cell membrane isn't present or 9 protected, like in a fungal spore or an anthrax 10 spore; right?			
11 A. If there was a membrane --			
12 MR. KREMEN: Objection to form.			
13 THE WITNESS: If there was a membrane 14 present, we're looking at what -- let me give you 15 an example. If you're looking at enveloped 16 viruses, there are some that have a membrane. 17 Others do not. So what you're looking at is the 18 effect -- and it's a chemical effect, essentially, 19 of the action of the benzalkonium chloride on the 20 membrane of the microorganism that we're 21 questioning.			
22 BY MS. PETERSON:			
23 Q. Okay. And that biocidic activity of 24 benzalkonium chloride, that's something that's 25 been known and it's been used for that purpose for			
	131		132
		1 Q. So to function as described in the 2 claims of the '802 patent, does the formulation 3 need to have all of those ingredients?	
		4 A. I believe they do. That it does, yes.	
		5 Q. And then you mentioned this earlier, but 6 the patent goes on and includes ten tables 7 describing typical formulations; right?	
		8 A. Yes.	
		9 Q. Okay. And it's not a specific 10 individual formulation disclosed in those tables, 11 but rather a list of ingredients with ranges for 12 the amounts of each ingredient; right?	
		13 A. Yes.	
		14 Q. So within each table, there can be some 15 variation in terms of how much of each ingredient 16 is used; right?	
		17 A. Yes.	
		18 Q. So would it be fair to say then that the 19 patent lists more than just ten discrete 20 formulations?	
		21 A. Multiples. In the cases of each of the 22 tables it can give you a variety of choices.	
		23 Q. Yeah, because I think water is the 24 primary ingredient in most of these, and it ranges 25 anywhere from 52 to 88 percent; right?	

Transcript of Edward A. Lemmo, Ph.D.

34 (133 to 136)

October 24, 2022

	133		135
1 A. Yes. And it's an important component		1 present itself as more of a problem than a benefit	
2 for the other materials to function.		2 associated with using that ingredient in the	
3 Q. Okay. And then these tables include		3 formula.	
4 anywhere between 12 to 18 ingredients each; right?		4 Q. Okay.	
5 A. I would safely -- I haven't counted		5 A. So in any formulation, regardless if	
6 them, but I would safely say yes. I assume that		6 it's nutritional or otherwise, we, in formulating	
7 you did count it to give me that number. That's		7 the product, have to consider what is the	
8 fine.		8 tolerance level for ingredients and what would be	
9 Q. It's pretty specific.		9 the benefit level to effect the outcome of the	
10 Okay. And then I saw that a few of the		10 formulation.	
11 tables also list benzalkonium chloride?		11 Q. Sure.	
12 A. Yes.		12 And so, likewise, varying the percentage	
13 Q. And benzalkonium chloride is always		13 of the ingredients could also change the potency	
14 identified in the range of .25 to 1 percent.		14 or the efficacy of the formulation; right?	
15 A. Yes, I think that's related to the		15 A. Absolutely. Absolutely.	
16 standard that's allowable.		16 Q. And varying the percentage of	
17 Q. Okay. So is that the effective		17 ingredients could also change the consistency of	
18 concentration of benzalkonium chloride that's		18 the formulation?	
19 needed to function in the claimed invention?		19 A. Yes, it could fall out of uniformity.	
20 A. I believe so.		20 And that's why in many instance stability studies	
21 Q. Okay.		21 are conducted on formulas when they are	
22 A. Yes.		22 conceptualized to the point where, as we were	
23 Q. Okay.		23 speaking before, are brought into the laboratory	
24 MS. PETERSON: We could take that down.		24 setting for the testing that's required to	
25 MR. KREMEN: It's now 1:47. Do you		25 demonstrate uniformity of dose and consistency of	
	134		136
1 think we might want to have a break at this point?		1 ingredient and stability studies. That's all	
2 MS. PETERSON: Yeah, sure, we can do		2 something that would then be evaluated that the	
3 that.		3 formula does, in fact, do what you claim it's	
4 MR. KREMEN: Ten minutes?		4 going to do.	
5 MS. PETERSON: Yep, that's good.		5 Q. And changing the ingredients or the	
6 THE VIDEOGRAPHER: We're going off the		6 percentage of the ingredients could also have an	
7 record. The time is 1:48 p.m.		7 impact on the adhesive properties of the	
8 (Recess from the record.)		8 formulation?	
9 THE VIDEOGRAPHER: We're back on the		9 A. If it's one of the ingredients that is	
10 record. The time is now 2 p.m.		10 associated with either adhesion or cohesion, the	
11 BY MS. PETERSON:		11 answer is yes.	
12 Q. Okay. Dr. Lemmo, I actually had just		12 Q. Okay.	
13 one other follow-up question about the		13 MS. PETERSON: Let's pull up Dr. Lemmo's	
14 formulations listed in the '802 patent.		14 claim construction declaration, and we will mark	
15 A. Sure.		15 this as Exhibit 17.	
16 Q. Would you agree that varying the		16 (Lemmo Deposition Exhibit 17 was marked	
17 percentage of the ingredients listed in those		17 for identification and attached to the	
18 formulations can change the potency of the		18 transcript.)	
19 formulation?		19 THE REMOTE TECHNICIAN: Stand by.	
20 A. It depends on the ingredient, yes. So		20 BY MS. PETERSON:	
21 that if, for example -- I don't see it in the --		21 Q. Dr. Lemmo, do you recognize Exhibit 17	
22 you know, I've have to scan it again. But if in		22 as a copy of your declaration in support of Trutek	
23 the case of benzalkonium chloride, if it's		23 Corporation's claim construction brief?	
24 exceeding that threshold limit, that could be very		24 A. Yes, I do.	
25 irritating for the user and, therefore, that may		25 Q. Okay. And if we move to the last page.	

Transcript of Edward A. Lemmo, Ph.D.

35 (137 to 140)

October 24, 2022

	137		139
1 Is that your signature?		1 MR. KREMEN: Yeah. Right.	
2 A. Yes, that is. And it's dated		2 BY MS. PETERSON:	
3 September 24th, 2022.		3 Q. "Based on the disclosures," you see	
4 Q. Okay. And do you see up at the top of		4 that?	
5 the page there's a header in blue that indicates		5 So, Dr. Lemmo, in this declaration	
6 it was filed on September 27th, 2022?		6 you're expressing the opinion that the claim	
7 A. Yes, I see that.		7 terms, "electrostatically inhibiting,"	
8 Q. Okay. Now, I notice that you do not		8 "electrostatically attracting," "adequate	
9 have a separate list of materials that you		9 impermeability," and "renders said particulate	
10 reviewed in connection with preparing this		10 matter harmless" are sufficiently clear and	
11 declaration; correct?		11 unambiguous; correct?	
12 A. That's correct.		12 A. That's correct.	
13 Q. Is everything that you considered or		13 Q. Okay.	
14 reviewed in forming the opinions expressed in the		14 MR. KREMEN: You're --	
15 declaration mentioned directly in the declaration?		15 THE WITNESS: Particularly to a person	
16 A. Yes. I'd have to just review that		16 of ordinary skill in the art.	
17 document again as we go through it.		17 BY MS. PETERSON:	
18 Q. Okay. Well, as of right now, are you		18 Q. Okay.	
19 aware of anything else that you reviewed in		19 A. And that's what I referred to earlier	
20 connection with preparing this declaration that		20 for this terminology relative to Dr. Amiji's	
21 you didn't identify?		21 report.	
22 A. No.		22 Q. Okay. So that was the standard that you	
23 Q. Okay. And of course you prepared this		23 applied here, "sufficiently clear and unambiguous	
24 declaration in support of Trutek's claim		24 to a person of ordinary skill"?	
25 construction positions in the litigation; right?		25 A. Yes, that's correct.	
	138		140
1 A. Correct, yes.		1 Q. Okay. So let's move ahead to paragraph	
2 Q. Okay. Let's go back to page 2. And,		2 32, which is going to be page 13 of the PDF.	
3 actually, we're going to be -- actually, page 3.		3 MR. KREMEN: 32.	
4 Let's go to the next page. This paragraph 5 --		4 THE WITNESS: Thank you for increasing	
5 nope, one page earlier.		5 the print size.	
6 MR. KREMEN: Liane, unfortunately, the		6 MR. KREMEN: Yeah, that helps.	
7 page numbers are hard to read. So I guess if we		7 THE WITNESS: It's very helpful.	
8 could also identify the page by just the first		8 MR. KREMEN: That really helps.	
9 sentence on the top, it would be helpful.		9 THE WITNESS: It's a lot of eyestrain.	
10 MS. PETERSON: Yeah. And where there's		10 BY MS. PETERSON:	
11 a clear paragraph number, I identify it that way		11 Q. Okay. And here, Dr. Lemmo, you're	
12 so that there's no ambiguity. It's just for		12 referring to what you discuss as the "hold"	
13 Jennifer sometimes it's easier to go to the page		13 function?	
14 of the PDF so we can move through the document		14 A. Yes.	
15 quickly.		15 Q. Of the claimed invention?	
16 BY MS. PETERSON:		16 A. Yes.	
17 Q. But looking at this page, which I think		17 Q. And you say that holding is based on the	
18 is page 3, we have paragraph -- do you see		18 adhesive and cohesive properties of the	
19 paragraph 5C?		19 formulation?	
20 A. It got cut off at the bottom.		20 A. Yes, that's correct.	
21 MR. KREMEN: It's 5C, though; right?		21 Q. Okay. And looking at the next	
22 Okay.		22 paragraph, 33, where you're talking about	
23 MS. PETERSON: 5C.		23 adhesion, the very last sentence you state that,	
24 MR. KREMEN: E or --		24 "This sets up a barrier of impermeability" --	
25 MS. PETERSON: C as in cat.		25 A. Correct.	

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Transcript of Edward A. Lemmo, Ph.D.

36 (141 to 144)

October 24, 2022

	141		143
1 Q. -- that -- "trapping a significant" --		1 I believe it's four hours. You know, a lot happens	
2 let me -- the entire sentence reads that, "This		2 within a four-hour window. So I believe that's	
3 sets up a barrier of impermeability trapping a		3 what -- you know, what's -- but I'm not certain.	
4 significant number of these particles outside the		4 You know, don't hold me to that one.	
5 nasal passageway"; right?		5 Q. Is it possible you're thinking of	
6 A. Correct.		6 marketing claims of the products that you looked	
7 Q. Okay. So the claimed formulation, once		7 at in the case?	
8 applied, it creates a thin film on the surface of		8 A. Thinking about it, it may not have been	
9 the skin; right?		9 in the patent itself that I specifically saw that.	
10 A. That's correct.		10 It was probably on the website for the product.	
11 Q. And that thin film, as recited in the		11 Q. Okay. So to the best of your knowledge,	
12 claims, is impermeable, meaning that it creates a		12 the patent doesn't define how much time is	
13 physical barrier?		13 sufficient to hold the harmful particles in place	
14 A. It -- yes, it creates a physical barrier		14 to allow them to be inactivated; right?	
15 outside of the body.		15 A. Yeah, at this point that's what I'm	
16 Q. Okay. And then that physical barrier		16 assuming, yes.	
17 traps those harmful particles from being inhaled		17 Q. Okay. So, I mean, how much time is	
18 into the respiratory system; right?		18 sufficient? Is an hour good enough?	
19 A. That's correct.		19 MR. KREMEN: Objection to form.	
20 Q. Okay. Let's move ahead two pages to		20 THE WITNESS: It's very vague. That's a	
21 paragraph 37.		21 very vague question of how much time. Because as	
22 In paragraph 37, you conclude that the		22 I said earlier, I use the product. I use the	
23 claim term "adequate impermeability is a property		23 product primarily during times when I'm in the	
24 of the applied formulation that allows the harmful		24 company of strangers, but in my own home where I	
25 particles to be held in place for a sufficient		25 am now speaking to you, I'm not using the product.	
	142		144
1 time to be inactivated"; right?		1 I So I don't feel that I need it. I may be coming	
2 A. That's correct.		2 in contact with animal dander, but I'm not	
3 Q. Okay. And so like we just talked about,		3 sensitive to the animal dander just because I have	
4 that's a physical barrier that allows the harmful		4 two cats.	
5 particles to be held in place --		5 BY MS. PETERSON:	
6 A. That's correct.		6 Q. Okay. So the amount of time that is	
7 Q. -- for a sufficient time? Okay.		7 sufficient, I guess it depends on the	
8 A. That's right.		8 circumstances of where the individual is or the	
9 Q. Now, "sufficient time," that's another		9 particular sensitivities of the individual or even	
10 relative term; right?		10 the nature of the material that's in the air?	
11 A. Yes. Again, we don't know when an		11 A. I would --	
12 individual will come in contact with a harmful		12 MR. KREMEN: Objection to form.	
13 microorganism that's in the airstream. So as I		13 THE WITNESS: I'm sorry, I didn't hear	
14 remember, the statements regarding the use of the		14 what --	
15 product is to use the product for a specific		15 MR. KREMEN: I said objection to the	
16 period of time before a person may want to		16 form of the question.	
17 reapply.		17 You may answer.	
18 Q. And then what does the patent say about		18 THE WITNESS: Okay. Just repeat, I'm	
19 how much -- what does the '802 patent say about		19 sorry, I lost my train of thought.	
20 how much time is sufficient?		20 BY MS. PETERSON:	
21 A. I believe it was a four-hour window. I		21 Q. Okay. So the amount of time that's	
22 have to go back and check that to be exact.		22 sufficient, it depends on the circumstances;	
23 Q. So you think four hours is specified in		23 right?	
24 the patent.		24 A. Yes, I agree with that, yes.	
25 A. For the use of the ingredients, I		25 Q. Okay. So it could depend on where the	

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<p>1 individual who's using the product is located?</p> <p>2 A. Yes. If you're in a highly polluted</p> <p>3 area, not necessarily pollution relative to</p> <p>4 bacterial pollution but irritants that may be in</p> <p>5 the air, if you happen to visit a place where</p> <p>6 people are smoking and you're highly sensitive to</p> <p>7 cigarette smoke or tobacco smoke, that may be a</p> <p>8 benefit for a person to possibly reapply. But I</p> <p>9 can't say definitely because I haven't done that</p> <p>10 testing.</p> <p>11 Q. So the amount of time that's sufficient,</p> <p>12 it could depend on the environment. It could</p> <p>13 depend on the particular sensitivities of the</p> <p>14 individual, as well; right?</p> <p>15 A. Yes.</p> <p>16 Q. It could also depend on the nature of</p> <p>17 the material that's in the air; right?</p> <p>18 A. Yes.</p> <p>19 Q. So certainly --</p> <p>20 A. Humidity. Humidity.</p> <p>21 Q. I'm sorry, I cut you off.</p> <p>22 A. No, humidity, a number of things that --</p> <p>23 you know, a person might actually touch their face</p> <p>24 a number of times, and by touching the face affect</p> <p>25 that which they applied. Not everyone can say</p>		<p>1 it.</p> <p>2 Q. Okay. So the cohesive property is what</p> <p>3 sets up the impermeable barrier; right?</p> <p>4 A. Along with that adhesive property. I</p> <p>5 think it's a combination of the two.</p> <p>6 Q. Okay. And then how --</p> <p>7 A. Because it's a -- I'm sorry, because</p> <p>8 it's a thin film.</p> <p>9 Q. Okay.</p> <p>10 A. So I think you have to have both, the</p> <p>11 ability to hold it to the skin and at the same</p> <p>12 time have that cohesive property that will act to</p> <p>13 attract any of those harmful agents, particles,</p> <p>14 that might be in the airflow.</p> <p>15 Q. Okay. So the impermeable barrier is a</p> <p>16 result of the adhesive and cohesive properties of</p> <p>17 the formulation?</p> <p>18 A. That's how I interpret it, yes.</p> <p>19 Q. And those adhesive and cohesive</p> <p>20 properties can be different depending on the</p> <p>21 ingredients and the percentages of those</p> <p>22 ingredients in the formulation; right?</p> <p>23 A. Yes.</p> <p>24 Q. Which in turn can impact the level of</p> <p>25 impermeability?</p>		
<p>1 without touching their face for a significant</p> <p>2 period of time. There are studies that</p> <p>3 demonstrate that. Exactly, Liane.</p> <p>4 Q. I do it all the time.</p> <p>5 A. Thank you for demonstrating.</p> <p>6 Q. I just broke my rule. I was just wiping</p> <p>7 my nose for people reading the transcript.</p> <p>8 A. Okay.</p> <p>9 Q. Okay. So in turn, that sufficient</p> <p>10 time -- I think you've also explained that the</p> <p>11 impermeability of the film is also related to this</p> <p>12 concept of allowing enough time to hold those</p> <p>13 particles in place; right?</p> <p>14 A. Yes, and it's also the stickiness, the</p> <p>15 tackiness of the material that plays an important</p> <p>16 part relative to the cohesive property of the</p> <p>17 material. And it's that cohesive property that</p> <p>18 sets up that impermeable barrier. And that's --</p> <p>19 when considered with the adhesive property and the</p> <p>20 cohesive property, as the patent states, that's</p> <p>21 the ability to hold. And it's essentially holding</p> <p>22 it outside of the body as opposed to depending</p> <p>23 upon that which is naturally present in the</p> <p>24 nostrils to try to protect an individual along</p> <p>25 with their immune system. That's how I interpret</p>	146		<p>1 A. Probably, yes.</p> <p>2 Q. And the ability of -- or the amount of</p> <p>3 time that the thin film acts as a barrier?</p> <p>4 A. Correct. But these would all be tests</p> <p>5 performed on the product beyond the scope of the</p> <p>6 patent. So, in other words, what I reiterated</p> <p>7 previously, in my experience in getting products</p> <p>8 on the market, if you have to do testing of your</p> <p>9 product, you have to -- in order to make the</p> <p>10 claims for your product, you need to generate the</p> <p>11 substantiation to support what you're saying about</p> <p>12 the product.</p> <p>13 So if I were putting a product on the</p> <p>14 market and I say reapply in four hours, I'm not</p> <p>15 taking that as an ambiguous period of time. I'm</p> <p>16 basing that on some sort of test parameter that I</p> <p>17 conducted in my laboratory or in the laboratory of</p> <p>18 the company before I go ahead and market that</p> <p>19 concept commercially.</p> <p>20 Q. Okay. And I think at the beginning of</p> <p>21 that answer you referred to that as being tests</p> <p>22 performed on the product beyond the scope of the</p> <p>23 patent. So is that referring to the fact that the</p> <p>24 patent doesn't describe any such testing of any of</p> <p>25 the formulations listed in the patent?</p>	148

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1 A. Well, it proposes -- the patent proposes 2 the concept of how it's going to work and its 3 methodology. Okay. There -- I don't think that 4 it's necessary to provide in the patent the end 5 point, you know, what exactly you're going to see 6 clinically. It's essentially presented as the 7 concept in the patent and then any subsequent 8 information that I'm referring to in the testing 9 would be done post patent, if that makes it clear.		1 combinations, require certain components that 2 might facilitate a better mixing of the 3 ingredients and holding together. It's kind of 4 like a jar of mayonnaise, you don't want -- you 5 can make your own mayonnaise and it can separate 6 out, but if you do it correctly, it should be 7 consistent.	
10 Q. Okay. But just even more simply, the 11 patent doesn't describe the results of any testing 12 of that nature of any of the formulations that are 13 listed; right?		8 Q. And an emulsifier would be required in 9 order for a formulation to function as claimed in 10 the patent?	
14 A. No.		11 A. Yes.	
15 Q. Okay. Let's look at paragraph 39. 16 Here, you state that the specification has a list 17 of the formulation's generic ingredients.		12 Q. And a neutralizing agent is necessary 13 for a formulation to function as claimed in the 14 patent?	
18 Do you see that?		15 A. In that specific range, yes.	
19 A. Yes.		16 Q. Okay. And an emollient would also be 17 necessary to function as claimed in the patent.	
20 Q. So this would be the categories of 21 ingredients; right?		18 A. Yes, because it's applied to the skin.	
22 A. That's what I referred to previously, 23 and I believe that's in the patent. It's recited 24 in the patent.		19 Q. Okay. Looking at the next page -- well, 20 actually, just starting at 41, here you're talking 21 about the ten example formulations in the patent; 22 right?	
25 Q. Okay. And is it your understanding that		23 A. Yes.	
1 each of these are required in order for a 2 formulation to function as claimed in the patent?	150	24 Q. Okay. And then moving on to the next 25 page, you state, "As long as the composition of	
3 A. I believe so, yes.		1 ingredients remains within the specified ranges, 2 the example formulations should function as 3 disclosed."	
4 Q. So a quarternary thickener would be 5 necessary?		4 Do you see that?	
6 A. Yes, and that would be benzalkonium 7 chloride that would be utilized. And some of 8 these components may have multiple roles. That so 9 benzalkonium chloride may act as a thickener but 10 it may also act as a preservative and it may also 11 act in the capacity of the cation contributor. It 12 will also act as the biocide.		5 A. Yes.	
13 Q. Okay. And conditioner would be required 14 for the formulation to function as claimed in the 15 patent?		6 Q. Okay. And what's the basis for that 7 statement?	
16 A. Yeah, I believe that's there primarily 17 because it's coming in contact with the skin and 18 so that certain ingredients or certain 19 components -- as a formulator you would 20 anticipate, you know, how the product is going to 21 be used and that you don't want to apply something 22 to the skin that's going to be irritating to the 23 skin.		8 A. That is what I mentioned earlier so 9 that, if I go back to my benzalkonium chloride -- 10 sometimes people will abbreviate that as BZK, just 11 so that it's not a mouthful of words. But 12 essentially what I'm saying is you really want to 13 have a level of ingredient that is safe and 14 effective as two key components. You don't want 15 to exceed that because it can potentially be 16 irritating.	
24 Also, sometimes ingredients, in order to 25 blend together, you know, when you're making		17 Remember, it's used as a disinfecting 18 agent, and if you touch detergent or some other 19 caustic material, you can get skin irritation, and 20 degree of sensitivity varies from person to 21 person.	
		22 Q. Okay. I guess I was wondering about -- 23 I also had a question about your conclusion that 24 the formulations should function as disclosed as 25 long as the ingredients remain within the	

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<p>1 specified ranges. So you're not offering the 2 opinion that as long as the ingredients remain 3 within those specified ranges, they will 4 necessarily and will always function as claimed?</p> <p>5 A. The ingredients should support the claim 6 that's made for the product.</p> <p>7 Q. I'm not sure I understand that.</p> <p>8 A. So, for example, if you're including -- 9 if you're including in your claim that the product 10 contains a biocide, you should have a biocide in 11 your product. And it should be at a range that is 12 useful and applicable for that type of a product.</p> <p>13 That's essentially what I'm referring to.</p> <p>14 Q. Okay. But we looked at the claims 15 earlier, and the claims don't recite all of these 16 different categories of ingredients; right?</p> <p>17 A. Right. That's correct.</p> <p>18 Q. Okay. So I guess what I'm asking is 19 based on what I see you say in paragraph 41, it 20 doesn't appear that you're providing the opinion 21 that as long as the ingredients in those ten 22 formulations remain within the specified ranges, 23 they will necessarily function as claims in the 24 '802 patent?</p> <p>25 MR. KREMEN: Objection; form.</p>		<p>1 BY MS. PETERSON:</p> <p>2 Q. Okay. And so as long as you stay within 3 the ranges in the tables of the patent, then the 4 formulation should work. It should have the right 5 level of adhesion and cohesion --</p> <p>6 A. I would hope so.</p> <p>7 (Cross talk.)</p> <p>8 A. I would hope so, yes.</p> <p>9 Q. And how do you -- do you know for 10 certain that every formulation within the stated 11 ranges will have that sufficient level of adhesion 12 and cohesion in order to create an impermeable 13 thin film that will work as described in the 14 claimed invention?</p> <p>15 MR. KREMEN: Objection; form.</p> <p>16 THE WITNESS: But I will answer. It 17 goes back to the categories. It goes back to the 18 categories that were mentioned previously. For 19 each recitation of the tables, I have not 20 personally done any work to test if that will work 21 the same, if Table 5 works the same as Table 7.</p> <p>22 At this point for what I've been exposed 23 to and what I've read, I cannot tell you in 24 certainty that 5 and 7 will work identically. I 25 assume that they do, but I haven't done any</p>	
<p>1 THE WITNESS: I'll try to clarify, if 2 that's okay. Some ingredients in products -- and 3 you'll see this on labels -- are considered inert. 4 They are really not there for a specific 5 functional property, but they are inert because 6 they're needed as a vehicle or a protective agent 7 or a cohesive agent, whatever that might be.</p> <p>8 So certain ingredients are placed, I'll 9 give you an example, in some formulations to 10 deliver simply a vitamin. You may put an 11 ingredient that's nonnutritive because to deliver 12 it, it would not be appropriate on its own. So 13 you have to provide it with something else. So 14 they facilitate -- as inert ingredients, they 15 facilitate the delivery of the product. That's 16 not site specific delivery, but just delivery of 17 the product in the specified form.</p> <p>18 So in this particular case where it is a 19 thin film that's going to be applied in and around 20 the nostrils, you don't want that material to drip 21 out, go into the channel, whatever area of the 22 face. You want it to remain in place, to hold it 23 in place for a specific period of time. And 24 ingredients facilitate each other in working kind 25 of like a concert when a formulation is developed.</p>	154	<p>1 testing on it. It would be unfair of me to make 2 that judgment.</p> <p>3 BY MS. PETERSON:</p> <p>4 Q. And what is that assumption based on?</p> <p>5 A. My experience primarily, my experience 6 in putting formulas together.</p> <p>7 Q. Okay. So that assumption, it's not 8 based on any information or testing that you read 9 in the patent; right?</p> <p>10 A. No, it's not.</p> <p>11 Q. Okay. Let's go to the next page of your 12 declaration. And do you see here there's a 13 heading that says "Disputed Claim Terms of the 14 '802 Patent"?</p> <p>15 A. Yes.</p> <p>16 Q. In this first paragraph, 45, you start 17 off by saying, "I am not an attorney. I 18 understand that the property of a claim being 19 indefinite is a legal determination, which is in 20 the province of the Court."</p> <p>21 And then you go on to say, "I will opine 22 on whether the disputed claim terms are 23 sufficiently unambiguous to enable one of ordinary 24 skill to understand and practice the inventions 25 set forth in the claims."</p>	156

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40 (157 to 160)

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	157		159
1 Do you see that?		1 Q. So about halfway through this paragraph,	
2 A. Yes.		2 you have a sentence that starts, "From the	
3 Q. Okay. So that last sentence, does that		3 remainder of each of Claim 1 or 2."	
4 accurately describe the standard that you applied		4 Do you see that? It's about halfway	
5 in forming your opinions?		5 through the paragraph.	
6 A. Yes, because I'm not a patent attorney,		6 A. Is it about halfway? I'm just trying to	
7 and my experience with patents has been primarily		7 find the -- but you can go forward. I'll follow	
8 to review patents that were presented to me to		8 you.	
9 give an opinion on. And that may be related to		9 Q. Yeah, I'm just going to read from your	
10 my -- not necessarily my academic experience but		10 report. So you explain that, "From the remainder	
11 more so in my corporate experience and as a		11 of each Claim 1 or 2, supported by the	
12 consultant to advise people if this is junk		12 specification, the claim elements involve	
13 science, does this mean anything, can you use it.		13 electrostatic fields"--	
14 Many people would come to a corporation		14 A. Yes.	
15 presenting their products or their concepts of a		15 Q. -- right?	
16 product or whatever in order to get the		16 Okay. So it's your understanding, then,	
17 corporation to back it and to do the necessary		17 that Claims 1 and 2 are directed to using these	
18 support to do further testing. And so to protect		18 electrostatic fields; right?	
19 the corporation, people like myself would be		19 A. The electrostatic field that's generated	
20 employed to do the evaluation. But I'm not an		20 by the formulation, yes.	
21 attorney. In every corporate setting I've worked		21 Q. Okay. And then you also go on to say	
22 with attorneys like yourself and Mr. Kremen, and		22 that, "Claims 1 and 2 refer to electrostatic	
23 they have asked me as many questions as you do,		23 attraction, which is a well-known scientific	
24 but not under these circumstances.		24 phenomenon even to a high school physics student";	
25 Q. So did Mr. Kremen provide you with an		25 right?	
	158		160
1 explanation of the legal standard that the		1 A. That's correct.	
2 court --		2 Q. Okay. And the formulation that's	
3 A. I had asked --		3 claimed in the '802 patent, it operates by this	
4 Q. -- uses to determine --		4 phenomenon of electrostatic attraction; right?	
5 A. Yeah, I had -- I'm sorry.		5 A. Yes, it's positive charged particles	
6 Q. -- whether a claim term is indefinite?		6 that attract the negative charged particles and	
7 A. I have asked him what the meaning is,		7 repel all the positive charged particles that may	
8 yes.		8 be in the atmosphere.	
9 Q. And did you include his explanation in		9 Q. Okay.	
10 your report?		10 MS. PETERSON: Let's move ahead two	
11 A. In my own words, yes.		11 pages, and we'll look at paragraph 51.	
12 Q. Okay. And those words are what we read		12 BY MS. PETERSON:	
13 here on paragraph 45?		13 Q. And, again, here you're viewing the	
14 A. That's correct.		14 claim term "adequate impermeability" in the	
15 Q. Okay.		15 context of what you describe as the "hold"	
16 A. Again, as a non-attorney, it's very		16 function of the claims; right?	
17 difficult for me to write legalese. I cannot do		17 A. That's correct. I consider that to be	
18 that. I tried my best, but I cannot.		18 one of the most important elements of the product.	
19 Q. Okay.		19 Q. Okay.	
20 MS. PETERSON: Let's go to the next		20 A. Or the patent.	
21 page, please.		21 Q. Okay.	
22 BY MS. PETERSON:		22 MS. PETERSON: Let's go on to the next	
23 Q. Paragraph 48, here you're discussing the		23 page, which is a continuation of paragraph 53.	
24 claim term "electrostatically inhibiting"; right?		24 BY MS. PETERSON:	
25 A. Yes, that's correct.		25 Q. So right at the top of this page, you	

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	161		163
1 state that, "Determination of adequate perm 2 ability is a term of degree"; right?		1 all tend to sneeze a little bit more during those 2 periods of time. It's because the levels are very 3 high. But throughout the year, we're exposed to 4 pollens, and it may not give us any degree of eye 5 irritation or nasal irritation causing us to 6 sneeze.	
3 A. Yes. 4 Q. And that in turn is going to depend on 5 the desired efficacy?		7 Q. Okay. And so using that example then, 8 if we're in allergy season where there's a high 9 amount of allergens in the air, you might need a 10 formulation that has increased adhesive and 11 cohesive properties with a more impermeable 12 barrier in order to sufficiently capture and hold 13 those particles and preventing them from -- or 14 inhibiting them from infecting the individual; 15 right?	
6 A. Yes. 7 Q. And the desired efficacy could also 8 depend on the nature of the harmful particles to 9 be captured by the formulation and infection 10 inhibited by?		16 A. Or you may want to apply the product 17 more frequently. So I -- 18 Q. And that would be because the adhesive 19 properties would impact how long the formulation 20 stays as a thin film?	
11 A. Yes. 12 Q. That was a bad sentence. 13 A. I know. I'm not correcting your 14 grammar. But just for clarification, my 15 understanding, again, it depends on, in a 16 microbiological standpoint, the type of organism, 17 the quantity of organism that a person would be 18 coming in contact with. 19 So you are assuming that you have this 20 capacity to trap -- and I think that's one of the 21 reasons why one of the -- one of the reasons why 22 they decided to change it from "preventing" to the 23 term "inhibiting" so that it's to trap a quantity 24 of harmful bacteria, you know, as best as you can 25 so that you reduce that tighter load that might		21 A. Well, how long it's going -- well, how 22 much you're coming in contact with -- you know, 23 some people come in contact with very polluted 24 environments, but on an average basis -- again, 25 this is not a prescription, but on an average	
1 be -- that the individual who would be classified 2 as the host would be experiencing. 3 Q. And so, of course, you know, the 4 particular nature of the particles will have an 5 impact on how many need to be held by the 6 impermeable thin film in order to prevent 7 infection; right? 8 A. That's correct. And that ties in with 9 my statement previously regarding the stickiness 10 or the tackiness of that material. It's very 11 important. Because you don't want these particles 12 to be bouncing off and going into the nasal 13 passage, at least that's how I understand the 14 concept. 15 Q. Okay. So if one were to design a 16 formulation that has, you know, reasonable 17 adhesion and cohesion and creates a thin film of 18 reasonable impermeability, that might be enough to 19 prevent infection by, you know, some microorganism 20 that's not particularly harmful or where the 21 tighter or the amount in the environment is 22 relatively low; right? 23 A. Yes, I think the example would be during 24 pollen season when you have high pollen counts. 25 Whether you have a pollen sensitivity or not, we	162	1 basis a product that you have sold 2 over-the-counter is something that's left up to 3 the individual to make a judgment as far as how 4 much and how often they use the product. 5 As I said earlier, in my own personal 6 experience of using the product, I use it when I'm 7 in a setting where I do have individuals who are 8 unknown to me. So if I get on a bus, I'm 9 definitely going to use this product. 10 Q. Okay. And then from the formulator 11 perspective, how does the formulator determine 12 what the desired level of permeability is? 13 A. The formulator would make that judgment 14 on the -- as I said earlier, the degree of 15 stickiness or tackiness of the actual product. 16 So, again, you would probably conduct experiments 17 to do that. 18 In this particular case, the process was 19 tested on the basis of the electrostatic surface 20 charge so that if the levels were there to 21 adequately meet a standard that they are claiming 22 that the product can do to attract these 23 particles, you would have that as your -- at least 24 in part, your substantiation that you set up that 25 field.	164

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42 (165 to 168)

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	165		167
1 Q. Okay. Isn't it also your opinion that 2 the electrostatic field that is generated alone is 3 not sufficient to meet the claim elements of 4 capturing and holding?		1 done. And I think the testing for the properties 2 that we're looking at relate back to the type of 3 surface charge that the product possesses. So 4 you're looking for -- as I'm speaking I'm shaking 5 the monitor here, I'm sorry.	
5 A. The electrostatic --		6 What you're doing is you're looking 7 essentially to set up that field where you're 8 setting up that barrier.	
6 MR. KREMEN: Objection to the form of 7 the question.		9 Q. Right. So --	
8 THE WITNESS: You may want to rephrase 9 that for me.		10 A. And you're measuring that electrostatic 11 charge. Because, again, you're looking at 12 positive and negative particles that have to be 13 trapped -- or negative particles that are in the 14 airstream that have to be trapped by the positive 15 field that's set up on that barrier.	
10 BY MS. PETERSON:		16 So, you know, you could look at it in 17 different ways. You could look at it from its 18 chemistry, but you could also look at it from the 19 physics of it, which is more related to that 20 electrostatic charge.	
11 Q. Isn't it also your opinion that the 12 electrostatic field that's generated from the 13 formulation, that alone is not sufficient to 14 achieve the claim elements of capturing and 15 holding?		21 Q. So when you say these concepts are 22 related, does that mean that you could have a 23 lower level of adhesion and cohesion in the 24 formulation as long as the formulation exhibits a 25 high electrostatic charge?	
16 MR. KREMEN: Same objection.			
17 THE WITNESS: And my answer is no. The 18 electrostatic field is -- or the electrostatic 19 charge that's set up is an important element of 20 how this product works. That's the methodology.			
21 BY MS. PETERSON:			
22 Q. Okay. And how does that relate, then, 23 to everything you were just discussing here about 24 the need to have adequate adhesion and cohesion 25 and impermeability to the thin film?			
	166		168
1 A. They all tie in, because the charge is 2 generated by those ingredients that's setting up 3 that impermeable setting. You don't want it to 4 bypass it. You want it to hold on to those 5 contaminants, be it biological or otherwise, so 6 that the person does not inhale large quantities. 7 And you want to do that outside of the respiratory 8 track, per se.		1 MR. KREMEN: Objection to the form of 2 the question.	
9 Q. Okay. So I asked you earlier how 10 does -- from a formulator perspective, how do they 11 achieve the desired permeability and you referred 12 to the adhesive and cohesive properties of the 13 formulation.		3 THE WITNESS: Can I answer?	
14 Do you recall that?		4 MR. KREMEN: Yeah, you can answer.	
15 A. Yes.		5 THE WITNESS: I mean, I feel that,	
16 Q. And how does the formulator -- oh, 17 sorry, strike that.		6 again, the amounts -- the amounts -- what has to 7 be provided is that you are able to set up that 8 impermeable field, that it has to be adequately 9 supplied. So, for example, if I simply take my 10 finger and touch, you know, the product and just 11 put it at the tip of my nose, I won't probably get 12 the same kind of effect as taking the product, 13 putting an adequate amount and spreading it around 14 the whole surface of the nose and maybe putting a 15 little bit in the nostrils to give me that much 16 more barrier of protection.	
18 Those adhesive and cohesive properties 19 can be different depending on the ingredients and 20 the percentages of ingredients used in the 21 formulation; right?		17 BY MS. PETERSON:	
22 A. Yes.		18 Q. So the -- to achieve the adequate 19 impermeability recited in the claims, that's also 20 going to depend on how the product is applied by 21 the user?	
23 Q. So how does the formulator decide how 24 adhesive it needs to be?		22 A. I would assume so, yes.	
25 A. Well, that's the testing that would be		23 Q. Okay.	
		24 A. But, again, a lot of that is tied in 25 with any of the materials that are supplied --	

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<p>1 excuse me, any of the materials that are supplied 2 with the product. So in my experience, when a 3 product has to be taken by mouth, you have to tell 4 the person, take by mouth because you don't know 5 how that person is going to utilize that product. 6 Q. Okay. So you're talking about 7 instructions that are provided with a commercial 8 product?</p> <p>9 A. That's correct.</p> <p>10 Q. You're not talking about instructions 11 that are provided in the '802 patent; right?</p> <p>12 A. Not in the patent; correct.</p> <p>13 Q. Okay. And what does the patent say 14 about what the desired level of impermeability is 15 for inhibiting infection caused by influenza 16 virus?</p> <p>17 A. I don't remember exactly if it states 18 that. So I'm at a disadvantage to respond to that 19 question right now.</p> <p>20 Q. So you're not aware of anything in the 21 '802 patent that identifies what the appropriate 22 level of permeability is for inhibiting infection 23 for any of the specific organisms or diseases that 24 are listed in the patent; right?</p> <p>25 MR. KREMEN: Objection to form.</p>	<p>169</p> <p>1 this point if there is. 2 BY MS. PETERSON: 3 Q. Okay. So that's your answer, you don't 4 remember? 5 A. I don't remember. 6 Q. Okay. 7 MS. PETERSON: Let's go to the next 8 page. 9 BY MS. PETERSON: 10 Q. And for reference, this is a 11 continuation of paragraph 55 of your declaration. 12 Here, you're talking about the claim term "renders 13 said particulate matter harmless"; right? 14 A. Yes. 15 Q. This is a long paragraph, but do you see 16 in the middle of the screen here there's a 17 sentence that says -- it starts "Further" and then 18 it says (at 3 -- that's Column 3, line 12 of the 19 patent. 20 Do you see that? 21 A. Yes. 22 Q. Okay. So you're referring to Column 3, 23 line 12 of the patent specification here. And you 24 quote a sentence that includes the language 25 "simultaneously inactivate, kill, or render</p>
<p>1 THE WITNESS: I don't think that was 2 necessary at the time that the patent was written. 3 It's simply presenting the concept of how this 4 thing should work, but not -- there's no efficacy 5 data, at least in my understanding, that would be 6 required to incorporate into the patent. 7 BY MS. PETERSON: 8 Q. Okay. Well, putting aside whether it's 9 required or not, you didn't see anything like that 10 in the patent; right? 11 A. Not to my recollection. 12 Q. No recommendations or instructions as to 13 the level of impermeability that's required for 14 particular harmful properties? 15 A. At this point, I probably -- I don't 16 recall if it is there. I may have read it, and I 17 just don't remember. I'm sorry. 18 Q. I didn't see it. I just want to make 19 sure that there isn't something that I was 20 missing. And it sounds like there wasn't? 21 MR. KREMEN: Objection. 22 THE WITNESS: I think I've read, you 23 know, the patent a number of times to feel 24 comfortable with it before I speak to you or 25 anybody else about it. But I can't remember at</p>	<p>170</p> <p>171</p> <p>1 harmless the microorganisms so trapped." 2 Do you see that? 3 A. Yes. 4 Q. And then you go on to say that, "The 5 significance of this statement is the correlative 6 conjunction 'or'?" 7 A. Yes. 8 Q. What's the significant of "or" to you 9 here? 10 A. Well, my interpretation is that the 11 benzalkonium chloride as the biocide should kill 12 the live organism or render it unavailable to the 13 host, render harmless -- or render harmless, 14 meaning if you have something that's not something 15 to be virulent but it can be irritant, that's what 16 I'm referring to. 17 So you could have -- as I mentioned 18 earlier, you could have exposure to particles in 19 smoke-filled air. You could have particles that 20 are classified as pollutants or xenobiotics, and 21 they do not necessarily pose a serious health 22 threat to the host, but they could be rendered 23 harmless by being neutralized by that 24 electrostatic charge that's on that membrane or as 25 a result of using the product around the nose.</p>

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Transcript of Edward A. Lemmo, Ph.D.

44 (173 to 176)

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	173		175
1 Q. So rendered harmless, in your 2 understanding then, can mean either inactivation 3 or killing?		1 A. No, that could be -- I would consider 2 that to be an extreme microorganism where large 3 numbers of those spores could potentially be very 4 detrimental to a person coming in contact with 5 that.	
4 A. More so trapping, trapping them so 5 that -- if it's not a viable material, why would 6 you want to kill it? You want to trap it. You 7 want to stop it from going into or prevent it 8 somehow from going into the nasal passages. 9 Inhibiting is going to slow things down. 10 Preventing is pretty much going to stop it.		6 Q. Okay. But --	
11 So I think what you want to do is you 12 could come in contact with the pollen at a lower 13 concentration and maybe the result of that will be 14 simply to sneeze, but you're not going to have a 15 severe allergic reaction. So it renders it 16 harmless. That's how I understood it.		7 A. No, I'm sorry. No, that's fine. You 8 can go forward.	
17 Q. Okay. I'm not sure I followed all of 18 that. So render harmless, it means trapped?		9 Q. Okay. But there are some microorganisms 10 where even if only a few of the organisms make it 11 into the body, that will be sufficient to cause 12 infection in that individual?	
19 A. I see that more as trapping it, yes.		13 A. Yes, that can happen, yes.	
20 Q. Okay.		14 Q. Let's move forward to -- one more page, 15 I think it's the last page of your declaration.	
21 A. Stopping it outside of the nasal cavity.		16 A. Okay.	
22 Q. Okay. And that trapping relates to the 23 electrostatic attraction?		17 Q. And here in paragraph 56, you're talking 18 about how patent claims are often incomprehensible 19 by laypersons; right?	
24 A. Correct.		20 A. Yes.	
25 Q. Okay.		21 Q. But you here are offering the opinion 22 that in the case of Claims 1, 2, 6, and 7 of the 23 '802 patent, the words appear to have their plain 24 meaning; right?	
	174	25 A. Yes.	
1 A. Or that electrostatic charge that's set 2 up as the barrier. Because if you look at it as a 3 wall of positive charge, anything that's going to 4 pass towards that wall that's set up is going to 5 stick to it.			176
6 Q. Okay. Now, you also looked at the 7 prosecution history of the '802 patent; right?		1 Q. Okay. So you would agree that the claim 2 terms as used in the Claims 1, 2, 6, and 7 of the 3 '802 patent just use their plain and ordinary 4 meaning as understood by a person of skill in the 5 art?	
8 A. Yes.		6 A. By a person of ordinary --	
9 Q. Okay. And you recall that the claim 10 terms were changed from "preventing" to 11 "inhibiting"; right?		7 MR. KREMEN: Objection to form.	
12 A. Yes.		8 THE WITNESS: Can I answer?	
13 Q. And the examiner's rationale was that 14 preventing implies that all harmful particulate 15 matter is captured --		9 MR. KREMEN: Yeah, go ahead.	
16 A. Yes.		10 THE WITNESS: I felt that a person of 11 ordinary skill reading the claim -- and, again, 12 going back to my example of a student in high 13 school understanding basic physics and positive 14 and negative charges would be able to navigate 15 those statements.	
17 Q. -- as opposed to inhibiting, which could 18 allow some of the harmful particulate matter 19 through?		16 In my experience reading patents, some 17 of the patent claims are extremely written for a 18 person of very high-level understanding. And it 19 prohibits that average layperson to pick that up 20 and be able to interpret what is recited in the 21 body of the patent, as well as in the specific 22 claims.	
20 A. Yes.		23 BY MS. PETERSON:	
21 Q. Okay. Would you agree that something 22 that's very toxic or, you know, extremely 23 virulent, like anthrax, if even a small amount 24 gets through, that that would not be rendering it 25 harmless?		24 Q. Okay. But that's not what you 25 understand to be the case for the '802 patent	

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Transcript of Edward A. Lemmo, Ph.D.

45 (177 to 180)

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1 claims; right?		1 Q. Okay. And you're not aware of anything	
2 A. I understand that the '802 patent claims		2 else any other documents or information that you	
3 are written in language that should be understood		3 reviewed in forming your opinions that aren't	
4 by a person of ordinary skill.		4 mentioned in the report?	
5 Q. Okay. So there's no particular		5 A. I'm sorry, I was just distracted by	
6 essential meaning to any of the particular claims		6 something. Just please repeat the question, I'm	
7 apart from what a person of ordinary skill in the		7 sorry.	
8 art would understand to be their plain and		8 Q. You're not aware of anything else, any	
9 ordinary meaning?		9 other documents or other information that you	
10 MR. KREMEN: Objection.		10 reviewed in forming your opinions that aren't	
11 THE WITNESS: To be perfectly honest, I		11 specifically mentioned in the report?	
12 looked at that patent, and I see a very simple		12 A. No. No, there's nothing else.	
13 concept being presented with a simple solution so		13 Q. Okay. And I think we established this	
14 that a person of ordinary skill should be able to		14 earlier, this report was prepared in response to	
15 read that and have some degree of understanding of		15 Dr. Amiji's opening expert report on invalidity;	
16 what's in those claims.		16 correct?	
17 MS. PETERSON: Okay. I'm at a good		17 A. That's correct.	
18 stopping point right now. Let's go off the		18 Q. Okay. And other than your opinion	
19 record.		19 directed to the enablement of the Rolf patent	
20 THE WITNESS: Okay.		20 application, your report does not provide any	
21 THE VIDEOGRAPHER: We're going off the		21 other opinions with respect to any of the other	
22 record. The time is now 3 p.m.		22 prior art identified and relied upon by Dr. Amiji;	
23 (Recess from the record.)		23 right?	
24 THE VIDEOGRAPHER: We're back on the		24 A. That's correct.	
25 record. The time is now 3:12 p.m.		25 Q. And with respect to the Rolf patent	
	178		180
1 BY MS. PETERSON:		1 application, your report does not provide any	
2 Q. Dr. Lemmo, I'll ask you again, have you		2 opinions with respect to whether the claims of the	
3 discussed the substance of your deposition		3 '802 patent would be obvious in view of Rolf in	
4 testimony with anybody during any of the breaks		4 combination with any other prior art; right?	
5 that we've taken today?		5 A. That's correct.	
6 A. No, I did not.		6 Q. Okay.	
7 Q. Okay. Thank you.		7 MS. PETERSON: Let's turn to page 6,	
8 Okay. I'd like to turn back to your		8 which is page 7 of the PDF.	
9 responsive report.		9 BY MS. PETERSON:	
10 MS. PETERSON: We can pull that up.		10 Q. And this is the section of your opinion	
11 It's Exhibit 14.		11 relating to the "hold" function; right?	
12 MR. KREMEN: 14. Responsive report on		12 A. Yes.	
13 validity.		13 Q. Okay. So looking at the second	
14 BY MS. PETERSON:		14 sentence, your opinion is that the claimed	
15 Q. So, Dr. Lemmo, I did not see a separate		15 invention uses electrostatic forces to attract	
16 list of materials that you reviewed in connection		16 particulate matter before entering the nasal	
17 with preparing this report; is that right?		17 passageway; right?	
18 A. That's correct. Anything, if I had		18 A. That's correct.	
19 additional materials, would have been submitted.		19 Q. But that's --	
20 Q. Okay. So would it be fair to say, then,		20 MR. KREMEN: That's -- you're	
21 that everything you reviewed or considered in		21 misquoting. Before entering the body's	
22 forming the opinions expressed in your responsive		22 respiratory system.	
23 report would have been cited directly in your		23 MS. PETERSON: Okay.	
24 report?		24 BY MS. PETERSON:	
25 A. Yes.		25 Q. Well, looking at the beginning of the	

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46 (181 to 184)

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	181		183
1 sentence, it states that "the product attracts 2 particulate matter from the airflow before 3 entering the nasal passageway using [sic] 4 electrostatic forces"; correct?		1 Q. Okay. So a formulation that exhibits an 2 electrostatic charge upon application to the skin 3 might not necessarily have the right amount of 4 adhesion or cohesion to perform that "hold" 5 function of the claims; right?	
5 A. That's correct. And the nasal passage 6 is considered physiologically a part of the 7 respiratory system.		6 A. That's correct.	
8 Q. Okay. Now, you go on to then say, 9 though, that "this alone is insufficient to 10 protect the individual from harmful particulate 11 matter entering the body's respiratory system"; 12 right?		7 MR. KREMEN: Objection to form. 8 BY MS. PETERSON:	
13 A. That's correct.		9 Q. So, in other words, a formulation or a 10 composition would need more than just a positive 11 charge to meet Claims 1 and 2 of the '802 patent?	
14 Q. Okay. So the electrostatic force 15 created by the formulation alone does not protect 16 the individual from harmful particulate matter 17 entering the body, and likewise would not protect 18 that individual or inhibit infection from those 19 materials; right?		12 A. Well, you want the material to adhere, 13 or you want it to remain being held by the 14 material that you're applying to the skin. And 15 that's what I see as an important thing. Just 16 having the electrostatic charge without the 17 ability to hold the product, an electrostatic 18 field could either repel or attract different 19 things. And that's -- you know, that's one aspect 20 of it.	
20 MR. KREMEN: Objection to form. 21 You may answer.		21 I think the other part is really -- or 22 what I consider to be an extremely important part 23 is that "hold" function, and that's why I probably 24 was more focused at the time that I wrote this 25 document.	
22 THE WITNESS: The electrostatic charge 23 addresses the negatively charged particles that 24 are in the airflow, but it does not address 25 anything else. So if particles in the airflow are	182		184
1 negatively charged, the positive charge of the 2 product is going to be a significant player. 3 I think my point in this paragraph is 4 the importance of the "hold" function. You don't 5 want particles to be bouncing off that surface 6 where the product had been applied and then picked 7 up into the nasal passage.		1 Q. So let me just see if I can repeat that 2 because I just want to make sure I have an answer 3 to my question.	
8 BY MS. PETERSON: 9 Q. Okay.		4 So a formulation that exhibits an 5 electrostatic charge upon the application to the 6 skin might not necessarily have the right amount 7 of adhesion or cohesion to perform that hold 8 function, which is also a necessary component of 9 the claims; right?	
10 A. So hold -- I keep going back to that 11 "hold" function because it's inhibiting them from 12 going into that respiratory system.		10 A. Yes, that's correct.	
13 Q. Okay. So, in other words, the 14 electrostatic charge of the formulation alone is 15 not sufficient for a product to function, 16 according to the claim. It also requires this 17 "hold" function that's recited in the claim, as 18 well; right?		11 Q. Okay. Let's move ahead to -- I think 12 it's page 9 of your report. It's page 10 of the 13 PDF. And this is the section where you discuss 14 the Rolf patent application; correct?	
19 A. Yes. I would agree with that, yes.		15 A. Yes, that's correct.	
20 Q. Okay. And that "hold" function -- we've 21 covered this repeatedly, but it's related to those 22 adhesive and cohesive properties of the 23 formulation and the permeability of the film upon 24 application of the formulation; correct?		21 MR. KREMEN: That's the -- where it says 22 paragraph 3, "The Rolf Patent Application"?	
25 A. Exactly, yes.		22 MS. PETERSON: Yeah, I'm not sure if 23 it's a paragraph or a section heading, but yes.	
		24 MR. KREMEN: Yeah, right.	
		25 MS. PETERSON: "3, Rolf Patent Application, that's where we are."	
		23 BY MS. PETERSON: 24 Q. Okay. You understand that essential 25 oils are cationic; right?	

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47 (185 to 188)

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	185		187
1 A. That's correct.		1 of applications, particularly for therapeutic --	
2 Q. Okay. And so when essential oils are		2 excuse me, their therapeutic uses. One of the	
3 applied to the skin, they will exhibit a surface		3 problems associated with essential oils -- I've	
4 electrostatic charge?		4 got something in my throat.	
5 A. That's correct.		5 One of the problems associated with	
6 Q. Okay. On the next page, if we scroll		6 essential oil is that essential oils need to be	
7 down, the first full paragraph, you note that		7 standardized. That indicates the fact that a	
8 there are some "limitations associated with the		8 standardized essential oil is derived from the	
9 use of essential oils"; right?		9 same part of the plant. It's a seasonal variation	
10 A. Yes, that's correct.		10 component. Its chemistry may change, and there	
11 Q. So they may have skin irritating		11 could be also some changes in its relative ratios	
12 properties?		12 to other components within that plant.	
13 A. Correct.		13 So for that reason some of these	
14 Q. Or severe toxicity profiles?		14 products or some of these oils, like limonene, for	
15 A. Correct.		15 example, can present itself as a very useful item	
16 Q. And that would depend on the amount that		16 in something like a hand sanitizer, but not	
17 is used of the essential oil; right?		17 necessarily a useful item when applied to the	
18 A. That would be one component, yes.		18 skin.	
19 Q. And that would also depend on the		19 When I read the Rolf patent, I took into	
20 concentration of the essential oil within the		20 consideration reports that I've reviewed or papers	
21 product; right?		21 that have been written on the subject matter, I	
22 A. Correct.		22 did not spell them out but just wanted to call the	
23 Q. So not all essential oils in all		23 attention to anybody who would read my report to	
24 concentrations and in all amounts will cause skin		24 the fact that there is documented evidence for	
25 irritation; right?		25 irritating properties.	
	186		188
1 A. Correct.		1 Q. Okay. My question was just a little bit	
2 Q. And not all essential oils in all		2 more basic. The literature that you are referring	
3 concentrations and in all amounts will be toxic		3 to, it's not cited in your report; right?	
4 either; right?		4 A. That's correct.	
5 A. That's correct.		5 Q. So we have no way of knowing what	
6 Q. Okay. So in the second sentence here		6 essential oils are being discussed under what	
7 you refer to reports in the literature.		7 context; right?	
8 A. Yes.		8 A. That's correct.	
9 Q. Do you see that?		9 Q. Okay.	
10 A. Yes.		10 A. That's correct.	
11 Q. What literature are you referring to?		11 Q. And were these reports in the literature	
12 MR. KREMEN: Where are you referring to?		12 something that you reviewed in connection with	
13 THE WITNESS: Second paragraph. Line 2,		13 forming your opinions, or are these just things	
14 second paragraph.		14 that you remember reading over the course of your	
15 MR. KREMEN: Starting with "While the		15 career?	
16 patent application suggests a mechanism"?		16 A. I think it's a combination of both.	
17 THE WITNESS: No, above that.		17 Q. Okay. So there are some literature	
18 MR. KREMEN: Okay.		18 references that you reviewed when performing -- or	
19 BY MS. PETERSON:		19 when forming your opinions and writing this report	
20 Q. So what literature are you referring to		20 that are not actually identified here?	
21 here?		21 A. That's correct. That's correct.	
22 A. A number of -- I did not specify in this		22 Q. Okay. And I assume that those reports	
23 document the literature that I referred to on		23 that you're referring to in the literature, those	
24 essential oil. Because in the natural products		24 were to specific essential oils as opposed to	
25 industry, essential oils are employed in a variety		25 general statements about all essential oils;	

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48 (189 to 192)

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	189		191
1 right?		1 A. Yes.	
2 A. Yes, that's correct. Because many		2 Q. Now, looking at -- let's skip ahead two	
3 essential oils are used in cosmetic agents, as		3 pages to the last paragraph of your section on	
4 well. And they're applied to the skin. So		4 Rolf. So this would be page 12 of the PDF. Okay.	
5 they're not irritating at the levels that they are		5 So --	
6 recommended.		6 MS. PETERSON: Can you go up a little	
7 Q. Yeah. And I would assume that if		7 bit? That's great.	
8 they're used in cosmetics, they would be applied		8 BY MS. PETERSON:	
9 to skin on the face --		9 Q. So you also offer the opinion that the	
10 A. Yes.		10 patch described in Rolf would not function as	
11 Q. -- near the nose?		11 described in that application; right?	
12 A. Yes, or wherever. But, yes, you're		12 A. That's correct.	
13 absolutely right. And if they're used in a soap,		13 Q. Okay. And so that would be your opinion	
14 you're applying it all over the body.		14 that the Rolf patent application is not enabled?	
15 Q. Okay. Would you agree that whether a		15 A. Yes, that's my conclusion. I felt that	
16 particular ingredient exhibits an electrostatic		16 it wasn't really -- the way it's presented, that	
17 charge that's an inherent feature or property of		17 the claims really would not work as they're	
18 that ingredient?		18 stated.	
19 A. Yes.		19 Q. Okay. So your opinion is based on the	
20 Q. And the '802 patent claimed invention is		20 conclusion that the claims of Rolf would not work?	
21 relying on that inherent feature of those		21 MR. KREMEN: Objection to form.	
22 ingredients that have positive charges; correct?		22 THE WITNESS: The fact that he's using	
23 A. That's correct.		23 essential oils as the primary component, I just	
24 Q. And you read the Rolf patent		24 felt in my review of the patent that it really	
25 application; right?		25 wasn't -- I didn't think of it as really a quality	
	190		192
1 A. Yes, I did.		1 scientific proposal in the patent.	
2 Q. And you understand that Rolf explains		2 BY MS. PETERSON:	
3 that the formulations it discloses have biocidic		3 Q. Okay.	
4 properties; right?		4 A. And so I kind of discredited the Rolf	
5 A. Yes, Yes, I have.		5 patent as a useful argument against the '802	
6 Q. Yes, you understand that Rolf discloses		6 patent.	
7 that its formulations have biocidic properties?		7 Q. Okay. And so the basis for your	
8 A. Yes, that's correct.		8 opinion, then, is centered on the fact that it	
9 Q. Okay. And those formulations disclosed		9 uses essential oils; is that right?	
10 in Rolf, Rolf explains that they can be used for		10 MR. KREMEN: Objection to form.	
11 the prevention of diseases associated with		11 THE WITNESS: It's a questionable	
12 airborne pathogens and respiratory tract		12 application and a questionable theory that's being	
13 pathogens?		13 presented. And some of the points of the	
14 A. Yes.		14 essential oil, as I mentioned before, has to do	
15 MR. KREMEN: Objection to form.		15 with standardization of those oils. You may see	
16 BY MS. PETERSON:		16 it sometimes. You may not always. So I didn't	
17 Q. And it's also your understanding that		17 feel that it provided adequate foundation.	
18 Rolf explains that these airborne pathogens and		18 BY MS. PETERSON:	
19 respiratory tract pathogens are inactivated upon		19 Q. Do you dispute Rolf's point that	
20 contact with the essential oil?		20 essential oils can be used to inactivate airborne	
21 A. Yes.		21 pathogens and respiratory tract pathogens?	
22 Q. And you also understand that Rolf		22 MR. KREMEN: Objection to the form.	
23 discloses the use of additional ingredients in its		23 THE WITNESS: Only on the basis that	
24 formulation, including antimicrobial agents such		24 it's cationic in nature. So it's providing a	
25 as benzalkonium chloride?		25 positive charge. There's no reference in Rolf to	

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49 (193 to 196)

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	193		195
1 the whole concept of holding. There's no holding 2 mentioned in Rolf. And that, as I go back to my 3 previous statements, was an important aspect of 4 the '802 patent. 5 BY MS. PETERSON: 6 Q. Okay. But you do agree that the 7 essential oils in Rolf are cationic and therefore 8 would exhibit an electrostatic charge; right? 9 A. Yes. 10 Q. And you testified earlier that that 11 concept is related to the holding concept; right? 12 MR. KREMEN: Objection. 13 THE WITNESS: It is related, but there's 14 more to that. 15 BY MS. PETERSON: 16 Q. Okay. Now, the adhesive -- the level of 17 adhesion and the level of cohesion provided by a 18 formulation, those would also be inherent 19 properties of a particular formulation; right? 20 A. Correct. 21 Q. Okay. 22 MR. KREMEN: Liane, are we still 23 speaking about Rolf? 24 MS. PETERSON: Yeah. 25 MR. KREMEN: Okay.		1 that you bring up for nonobviousness. 2 Q. Okay. Let me -- I can break that down 3 for you a little bit better. 4 A. Yeah, it would be helpful. 5 Q. Okay. So you say right here in the 6 first sentence that, "I understand that commercial 7 success of a patented product tends to show that 8 the patented claims are not obvious provided that 9 the commercial success is due solely to the 10 patented claims." 11 Do you see that? 12 A. Right. Yes. 13 Q. So is that the standard that you applied 14 in your analysis? 15 A. Right. In other words, what I was 16 trying to say here, if in the '802 patent, if it 17 doesn't do what they say it's doing, you won't 18 have 7 million sales worldwide or whatever that 19 number is domestically, et cetera. People would 20 not be using the product. It doesn't work. So 21 that contributes to the fact that it is a novel 22 invention, because it's continuously being used 23 and continues to be sold. 24 Q. Now, you would agree that there could be 25 non-patented features of a product that drive	
	194		196
1 MS. PETERSON: We're discussing Rolf. 2 MR. KREMEN: Okay. 3 MS. PETERSON: But also generally asking 4 to confirm his understanding of some of the points 5 we've discussed. 6 MR. KREMEN: Okay. I just wanted to 7 make sure that we had some context. 8 BY MS. PETERSON: 9 Q. So, Dr. Lemmo, then is it correct to 10 understand that you don't have any issue with Rolf 11 using -- or applying the formulation through a 12 device, like a patch? 13 A. No, I have no objection to that. 14 Q. Okay. The last section of your 15 responsive report relates to commercial success. 16 Do you see that heading, No. 4? 17 A. Yes. 18 Q. What standard did you use when 19 determining whether Trutek's products demonstrate 20 commercial success as being relevant to the 21 question of nonobviousness? 22 A. Well, I felt that commercial success was 23 based upon the number of units that the product 24 was -- that the product has been sold. I use 25 that. I'm trying to understand the relationship	1 demand for the product; right? 2 A. Sure. 3 Q. Did you consider whether any 4 non-patented features of Trutek's products 5 contributed to its sales? 6 MR. KREMEN: Objection to form. 7 THE WITNESS: I don't know what those 8 might be. 9 BY MS. PETERSON: 10 Q. Okay. So that answer is no, I guess? 11 A. If you could give me -- no, the reason 12 why I say that is, you know, if you could give me 13 an example of what you're referring to, I might be 14 able to give you an opinion. 15 Q. I don't have a specific example, I'm 16 just asking you if you considered whether there is 17 a possibility that non-patented features of 18 Trutek's product could drive the demand for the 19 product? 20 A. It's possible. 21 MR. KREMEN: Objection. 22 BY MS. PETERSON: 23 Q. And you did not consider that in your 24 analysis; right? 25 A. No.		

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50 (197 to 200)

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	197		199
1 Q. Okay. Now, this statement in the first 2 sentence of Section 4, where did you obtain that 3 understanding from?		1 A. As a result --	
4 A. I don't remember exactly that. As I 5 said, my thought process for the concept -- the 6 novel concept. I tried to tie that in with my 7 understanding of what happens with products on the 8 market. That was my thinking at the time that I 9 wrote this.		2 Q. Okay. So repeat sales --	
10 Q. Okay. Now, in the next sentence, you 11 refer to, "Since the time the '802 patent was 12 issued in 2012, approximately seven million units 13 of the product based on this patent, have been 14 sold in the United States and internationally."		3 A. I'm sorry, so repeat sales is a 4 measure -- as I've been educated in the corporate 5 setting, repeat sales of a unit is a measure of 6 the product's success. And that's what keeps it 7 novel.	
15 Do you see that?		8 Q. Okay. So repeat sales is a factor that 9 you considered with respect to commercial success; 10 correct?	
16 A. Yes.		11 A. Yes, that's correct.	
17 Q. What product are you referring to?		12 Q. And your understanding that repeat sales 13 is relevant comes from your corporate experience?	
18 A. I'm referring to the nasal ointment, the 19 gel that was used.		14 A. Yes, I relied on that in making my 15 statements.	
20 Q. So I'm sorry, is this NasalGuard?		16 Q. Okay.	
21 A. NasalGuard, yes.		17 A. And in order to do that -- in order for 18 me to do that, because I can't find that sales 19 data or anything, I had to go back to Trutek and 20 find out from them -- I had to find out from them, 21 you know, what are you selling? How much do you 22 sell? Do you sell 500 units in 12 years or 23 whatever the period of time was? I have to get 24 some sense of how successful this is.	
22 Q. Okay. And is it all iterations of 23 NasalGuard or just one specific NasalGuard 24 product?		25 Q. Okay. And going back, you said that you	
25 A. I had -- I generated that piece of	198		200
1 information as a result of asking Mr. Wahi.		1 asked for information on one specific NasalGuard	
2 Q. Okay. So Mr. Wahi provided you with 3 information about how many units of a particular 4 NasalGuard product had been sold in the United 5 States?		2 product because of the fact of these repeat sales; 3 right?	
6 A. And internationally.		4 A. That's correct.	
7 MR. KREMEN: Objection.		5 MR. KREMEN: Objection to form.	
8 BY MS. PETERSON:		6 BY MS. PETERSON:	
9 Q. And do you know why -- or did you only 10 ask for information on sales for that one specific 11 product?		7 Q. So does that mean that Trutek's other 8 NasalGuard products don't have repeat sales?	
12 MR. KREMEN: Objection.		9 A. I don't know. I would assume that they 10 do.	
13 THE WITNESS: Yes.		11 Q. So how did you know that this particular 12 NasalGuard product had repeat sales?	
14 BY MS. PETERSON:		13 A. I did not know that before I asked 14 Mr. Wahi for the number of sales of the product he 15 has.	
15 Q. Why did you only ask for that one 16 product?		16 Q. So --	
17 A. Because I wanted to just understand how 18 much of the product is being sold. It was for my 19 own knowledge that the product has repeat sales. 20 In the document, I believe I go on to talk about 21 repeat sales of a unit.		17 A. I don't have sales data or marketing 18 information at my fingerprints.	
22 Q. Okay.		19 Q. Okay. So Mr. Wahi provided you with the 20 information about the one particular NasalGuard 21 product that had repeat sales?	
23 A. And that's how I was educated on 24 commercial success of a product.		22 MR. KREMEN: Objection.	
25 Q. Okay.		23 THE WITNESS: That was one that I asked 24 about. I didn't ask about any other product.	

Transcript of Edward A. Lemmo, Ph.D.

51 (201 to 204)

October 24, 2022

	201		203
1 BY MS. PETERSON:		1 A. Yes.	
2 Q. And going back to that again, why did		2 Q. But you're not sure whether those other	
3 you only ask about that one product?		3 Trutek patents that you reviewed cover the	
4 A. Because that's the product that I use.		4 NasalGuard products?	
5 Q. Okay. So do you know anything about the		5 MR. KREMEN: That's not what he said.	
6 sales of any of the other Trutek NasalGuard		6 BY MS. PETERSON:	
7 products?		7 Q. Can you answer, please?	
8 A. No, I don't.		8 A. Just repeat the question, I'm sorry.	
9 Q. So you have no idea if they're being		9 Q. Okay. You did look at Trutek's other	
10 sold at the same levels?		10 patents; correct?	
11 A. I don't know.		11 A. Yes. Yes, I did.	
12 Q. But it is your understanding that all of		12 Q. Okay. And you said you focused	
13 the NasalGuard products have the same exact		13 primarily on the '802 patent?	
14 formulation, with the exception of the scented		14 A. Correct. I looked at the '488 patent.	
15 product which includes an additional ingredient		15 I looked at the '481 patent.	
16 providing that scent; that's correct?		16 Q. And do those --	
17 A. That's the way I understand it.		17 A. Those are patents that I -- they	
18 MR. KREMEN: Objection.		18 focused -- one focused mostly on the method. The	
19 BY MS. PETERSON:		19 other one was on the formulation.	
20 Q. Okay. Let's go to the next page.		20 Q. And are you talking about the claims of	
21 In the first paragraph, the second full		21 those patents --	
22 sentence, you also explain that -- it looks like		22 A. Yes.	
23 you're explaining another factor you considered,		23 Q. -- or the disclosure of the patent?	
24 which is that, "Patent protection offers		24 A. The claims.	
25 additional support for a product to be considered		25 Q. And do the claims of the patent covering	
	202		204
1 as a success," right?		1 the formulation, do those read on the Trutek	
2 A. Yes.		2 NasalGuard product?	
3 Q. Okay. So it's your opinion that part of		3 A. It's been a while since I looked at it.	
4 the success of Trutek's NasalGuard product is the		4 I would have to go back and look at it again.	
5 result of it having patent protection?		5 Q. Okay. So as we're sitting here today,	
6 A. Yes.		6 you're not sure either way, whether the claims	
7 Q. And when you refer to patent protection,		7 of the earlier Trutek formulation patent cover the	
8 I assume you're talking about all of Trutek's		8 NasalGuard product?	
9 patents?		9 MR. KREMEN: Objection.	
10 A. Just the '802 patent.		10 THE WITNESS: I would have to refresh my	
11 Q. You've reviewed Trutek's other patents;		11 memory and reread.	
12 correct?		12 BY MS. PETERSON:	
13 A. Correct.		13 Q. Okay. Do you know when NasalGuard was	
14 Q. Do those other patents read on -- or do		14 first offered for sale in the United States?	
15 those other patents cover the Trutek products?		15 A. I believe that was the 2012. It's	
16 A. I primarily focused on the '802 patent.		16 possible, but I'm not certain. I do post a year.	
17 Q. Okay. So you aren't sure one way or the		17 Q. And when you obtained this information	
18 other whether any of Trutek's other patents cover		18 from Mr. Wahli, did he just give you the	
19 the Trutek NasalGuard products?		19 number 7 million units, or did he give you, like,	
20 MR. KREMEN: Objection.		20 sales records for that product?	
21 THE WITNESS: As I said previously, I		21 A. No sales records, no.	
22 focused primarily on the '802 patent.		22 Q. So he --	
23 BY MS. PETERSON:		23 A. He just gave me -- he just mentioned it	
24 Q. I mean, did you look at Trutek's other		24 to me.	
25 patents?		25 Q. Okay. So you had a conversation with	

Transcript of Edward A. Lemmo, Ph.D.

52 (205 to 208)

October 24, 2022

	205		207
1	Mr. Wahi, and he told you that the particular	1	THE WITNESS: That is one good example.
2	NasalGuard product that you use has sold 7 million	2	I could tell you from personal experience products
3	units sales since 2012?	3	that I've developed sell sometimes better in a
4	A. Yes.	4	foreign country because of the nature of the
5	Q. Okay. In that same sentence we were	5	product as opposed to domestically.
6	just looking at, you also say that because the	6	BY MS. PETERSON:
7	Trutek products "have been marketed successfully	7	Q. Okay. So the next sentence says that,
8	for ten years, this product line stands tall among	8	"The product has a domestic and international
9	products in this category."	9	presence which demonstrates that it has been
10	Do you see that?	10	reviewed for human use without prescription for
11	A. Yes.	11	the claimed properties established in the patent."
12	Q. And here, now it looks like you're	12	A. Yes.
13	talking about the entire Trutek NasalGuard product	13	Q. Can you explain what you mean by that?
14	line?	14	A. Okay. When a product is placed on the
15	A. Probably. As I said, to my knowledge,	15	market domestically and you make claims for the
16	there is an unscented version and a scented	16	product, the claims have to be substantiated and
17	version. And that's what I'm referring to.	17	usually submitted to one of the regulatory bodies.
18	Q. Okay. So you would agree then that the	18	Within a corporation, you have an internal
19	sales of the Trutek NasalGuard products are due at	19	regulatory body who reviews the product and
20	least in part to their marketing efforts?	20	reviews the claims that you're making about the
21	MR. KREMEN: Objection.	21	product and affirms the fact that what you're
22	THE WITNESS: The sales are essentially	22	saying about the product will, in fact, do what
23	based on the use by the consumer. So regardless	23	you state on your labeling.
24	of what their marketing efforts may be, even if	24	Q. Okay. So those are all related to
25	they don't do anything -- and they don't really.	25	statements made in the labeling for a product or
	206		208
1	I don't see much advertising for the product, to	1	in the advertisement for a product; correct?
2	be honest. But the sales of the product are	2	A. Correct. And it relates primarily to
3	really based upon, as I said before, repeat sales.	3	the regulatory affairs department.
4	If I buy the product, I buy a tube of the product,	4	Q. Okay. So you're not suggesting here
5	and I find that I'm -- I like the use of the	5	that the FDA reviewed information to confirm that
6	product and I feel comfortable using the product,	6	NasalGuard practices each and every element of the
7	I would go out and buy it again.	7	'802 patent claims; right?
8	BY MS. PETERSON:	8	MR. KREMEN: Objection.
9	Q. When did you first start using	9	THE WITNESS: No, I'm not saying that.
10	NasalGuard?	10	BY MS. PETERSON:
11	A. The first time that I used it was when	11	Q. Okay. So, rather, you're talking about
12	we had discussion related to Matrixx Initiatives.	12	the product being reviewed to substantiate claims
13	Q. So you were not using NasalGuard prior	13	that Trutek makes in its website or product
14	to being contacted by Trutek.	14	packaging or product labeling to make sure that
15	A. I had no idea of the product.	15	they're accurate?
16	Q. Would you also agree that the sales of a	16	A. If a product is on the market and in
17	product can depend, at least in part, on where	17	violation of the FDA, you would receive an FDA
18	those products are being sold?	18	letter, a warning letter, that your product is
19	A. Yes.	19	either misbranded or mislabeled. And to my
20	Q. So certainly, like, a sale on Amazon	20	knowledge, that doesn't exist. Otherwise, that
21	where consumers can identify the product by	21	product would be off the market at this point. No
22	searching, you know, that would be easier for a	22	retailer would carry that product.
23	consumer to purchase than if it was only available	23	Q. Sure. Okay.
24	through a distributor?	24	Now, at the bottom of this page, you
25	MR. KREMEN: Objection.	25	talk a little bit how the Trutek NasalGuard

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Transcript of Edward A. Lemmo, Ph.D.

53 (209 to 212)

October 24, 2022

	209		211
1 products operate.		1 A. I did not conduct any of that, no.	
2 A. The page has to be raised. I'm not		2 Q. Okay. But you did rely on some testing	
3 seeing --		3 of NasalGuard conducted by Dr. Burns and --	
4 MS. PETERSON: Yeah, can you scroll down		4 Mr. Burns and Dr. Ermakov; correct?	
5 a little bit. I'm looking at the last full		5 A. Yes, that's correct.	
6 paragraph. The last paragraph, so starting with		6 Q. Okay. And that of course was the	
7 "The commercial" -- there we go.		7 testing with respect to the conductivity or the	
8 BY MS. PETERSON:		8 electrostatic charge of the formulation?	
9 Q. Okay. So you talk about how 'The '802		9 A. The electrostatic charge, not the	
10 patent claims a product that electrostatically		10 conductivity.	
11 inhibits harmful airborne particles from infecting		11 Q. Well, they were testing -- you don't	
12 an individual."		12 disagree that they were testing the conductivity;	
13 And then you go on to say, 'This product		13 right?	
14 effectively prevents that from happening by		14 A. They were not testing conductivity.	
15 creating a positive electrostatic charge that		15 They were testing electrostatic charge.	
16 attracts the particles and holds the particles in		16 Q. Well, no.	
17 place until a biocide can inactivate them and		17 A. Conductivity --	
18 render them harmless"; correct?		18 Q. That's what they ultimately reported.	
19 A. That's correct.		19 A. Conductivity --	
20 Q. So that's your understanding of how		20 Q. But they were actually --	
21 NasalGuard operates.		21 A. No.	
22 A. That's my understanding of the		22 Q. -- measuring --	
23 mechanism, yes.		23 A. No. My understanding of conductivity is	
24 Q. Okay. So that electrostatic charge both		24 the placement of the electrode into the solution.	
25 attracts the particles and holds the particles in		25 The electrode -- and that's one of the reasons why	
	210		212
1 place; correct?		1 I wanted to witness this, to go there and see what	
2 MR. KREMEN: Objection.		2 they did.	
3 THE WITNESS: I think I reiterated the		3 Q. Okay. Regardless, the testing that you	
4 fact that the holding, that cohesive nature, was		4 relied on with respect to whether Trutek products	
5 aside from, that related primarily to that		5 practice the '802 patent claims, that would be the	
6 impermeability that was related. There were other		6 Burns and Ermakov testing about the surface	
7 ingredients.		7 electrostatic charge of the products; correct?	
8 BY MS. PETERSON:		8 A. That's correct.	
9 Q. But here you're saying that the		9 Q. Okay. And that's the information that	
10 electrostatic charge attracts the particles and		10 you relied on in forming your opinion that the	
11 holds the particles in place; correct?		11 commercial success of NasalGuard is due to the	
12 A. Yes. Yes.		12 claimed invention?	
13 Q. Okay.		13 MR. KREMEN: Jeez, objection to form.	
14 A. But there are other components to the		14 THE WITNESS: There's a -- the testing	
15 product.		15 demonstrates the fact that there is an	
16 Q. Okay.		16 electrostatic charge. So the claim that the	
17 A. For the holding function.		17 mechanism utilizing the electrostatic charge is	
18 Q. But certainly the electrostatic charge,		18 substantiated by the work of Dr. Ermakov as well	
19 in your opinion, here with respect to NasalGuard		19 as Mr. Burns in separate studies using either a	
20 performs both of those functions?		20 piece of paper or a physiologically useful agent,	
21 A. Yes.		21 namely, the pigskin that was done by Mr. Burns.	
22 Q. Okay. Now, you did not do a		22 BY MS. PETERSON:	
23 claim-by-claim analysis of whether the Trutek		23 Q. Okay. And you didn't do any other	
24 NasalGuard products practice each and every		24 testing of the level of adhesion or cohesion	
25 element of the '802 patent claims; correct?		25 provided by the NasalGuard formulation?	

Transcript of Edward A. Lemmo, Ph.D.

54 (213 to 216)

October 24, 2022

	213		215
1 A. Me personally, no.		1 started using the product in 2020. It was in and	
2 Q. And you're not aware of anybody else		2 around the time that we started learning more	
3 conducting that testing; correct?		3 about coronavirus, and I was looking for ways that	
4 A. I'm not aware of it, that's correct.		4 I can protect myself in addition to wearing the	
5 Q. And you didn't rely on it; right?		5 mask and being vaccinated.	
6 A. I would have mentioned it.		6 Q. Okay. So you did not use NasalGuard	
7 Q. And, similarly, you didn't rely on any		7 prior to 2020; right?	
8 testing or -- you did not rely on any testing of		8 A. I wasn't familiar with the product, as I	
9 the level of permeability of any thin film formed		9 stated earlier.	
10 by NasalGuard upon application of the product?		10 Q. Okay. So you don't know for certain	
11 A. No, I did not.		11 whether the '802 patent was marked on NasalGuard	
12 Q. Okay.		12 products that were sold prior to 2020; right?	
13 MS. PETERSON: Last page, can we turn		13 A. No, I don't know that.	
14 one more page forward.		14 Q. Okay.	
15 BY MS. PETERSON:		15 MS. PETERSON: We can take that exhibit	
16 Q. You also conclude here that, 'The patent		16 down.	
17 number of the '802 patent is clearly marked for		17 BY MS. PETERSON:	
18 every unit sold in the United States."		18 Q. I'd like to take a look at your -- let's	
19 Do you see that?		19 mark another exhibit. This is a list of materials	
20 A. Yes.		20 that you reviewed that was attached to your	
21 Q. And what's the basis for that assertion?		21 opening report.	
22 A. That's for patent protection but that		22 MS. PETERSON: Jennifer, I think it's	
23 the person -- again, if a person tries to market a		23 item No. 7. It says "Lemmo Materials Reviewed."	
24 similar product without that patent number, that		24 We'll mark this as Exhibit 17.	
25 could be a violation, in my opinion.		25 (Lemmo Deposition Exhibit 18 was marked	
	214		216
1 Q. Okay. Yeah, no, my question was just		1 for identification and attached to the	
2 how do you know that the patent number of the '802		2 transcript.)	
3 patent is clearly marked for every unit sold in		3 MR. KREMEN: 18. 17 was --	
4 the United States?		4 MS. PETERSON: Oh, yes, 18. Thank you.	
5 A. Oh, because I use the product.		5 BY MS. PETERSON:	
6 Q. Okay. So you looked at one of your		6 Q. Okay. Dr. Lemmo, do you recognize	
7 products, and you saw the patent number listed?		7 Exhibit 18?	
8 A. Yeah. And, you know, it would be		8 A. Yes.	
9 unusual for me to get a product that has a serial		9 Q. And this is a list of materials that you	
10 number and someone else get it without. That's		10 reviewed that you prepared and attached to your	
11 just part of quality control and quality assurance		11 opening report; correct?	
12 in the manufacturing sector of a business.		12 A. That's correct.	
13 Q. And it's your understanding that there		13 Q. Okay. Other than the materials listed	
14 could be potential liability if a company does not		14 here on Exhibit 18, did you review anything else	
15 include a patent marking on its product?		15 in forming your opinions stated in your opening	
16 MR. KREMEN: Objection to form.		16 report?	
17 THE WITNESS: It's not so much		17 A. Only the ones that are listed here.	
18 liability. It's more so protection of your		18 Q. Okay. Did you identify personally each	
19 product that it is patented.		19 of these -- well, never mind. Strike that.	
20 BY MS. PETERSON:		20 Okay. Item No. 6 refers to "Information	
21 Q. Now, you only --		21 on the NanoBio Protect product packaging."	
22 A. Because if it --		22 Do you see that?	
23 Q. -- started using NasalGuard in 2020 --		23 A. Yes.	
24 A. Probably it was early 2020. I had some		24 Q. And that would be your own personal	
25 serious illness in 2019, and as a result, I		25 copies of the product packaging that you had in	

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Transcript of Edward A. Lemmo, Ph.D.

55 (217 to 220)

October 24, 2022

	217		219
1 your possession?		1 be it to Mr. Kremen or Mr. Wahi or any other	
2 A. Whatever I was able to obtain on the		2 clients that I may have in the past or in the	
3 website for NanoBio.		3 hopefully future, you know, I provide them with	
4 Q. Okay. Item No. 5, copies of the portion		4 background information that I find. I'll do a	
5 of the BlueWillow website.		5 patent search.	
6 Do you see that?		6 Q. Okay. So is it your recollection that	
7 A. Yes.		7 these patents are directed to different	
8 Q. Did you identify those sections of the		8 oil-in-water emulsions?	
9 website yourself personally, or were you provided		9 A. It's possible that that's the case.	
10 them or directed to them by counsel?		10 Offhand, I don't have -- I apologize for not	
11 A. When I was retained by Mr. Wahi and he		11 listing the patent number and the descriptor on	
12 told me a little bit about the case, routinely in		12 this as a list. But I do have those files.	
13 order to familiarize myself, I'll do a quick		13 Q. But they were identified by you and	
14 search in the literature to what I could find out		14 reviewed by you for background purposes?	
15 about the company. BlueWillow was not a company		15 A. Yes, that's correct.	
16 that I was familiar with before Mr. Wahi had		16 Q. To further inform you about the products	
17 contacted me at that time.		17 at issue in the case?	
18 Q. And I assume that means you weren't		18 A. Yes. Just to familiarize myself with	
19 familiar with the NanoBio Protect product either?		19 what was going on. It's very difficult,	
20 A. Not at all.		20 especially when you're looking at a product that	
21 Q. Never came across it?		21 you have no knowledge of and claims that are being	
22 A. Not at all.		22 made, especially for the NanoBio product and what	
23 Q. Okay. And, actually, I just realized I		23 NanoBio was attempting to do with their	
24 mischaracterized something in that list. Item		24 products -- or rather -- I'm sorry, rather what	
25 No. 6, I can't remember if I said that that was		25 BlueWillow was attempting to do with their	
	218		220
1 NasalGuard product packaging or NanoBio Protect		1 products, including the NanoBio Protect product,	
2 product packaged. So let me ask you again.		2 so that I get a clearer picture of what the	
3 This NanoBio Protect product packaging		3 entity, what this business was all about.	
4 that you're referring to, is that something you		4 Q. Okay. And then to the best of your	
5 purchased, or was it provided to you?		5 recollection, there wasn't anything specific	
6 A. No, it was what I found on the Internet.		6 within any of these patents that you specifically	
7 Q. Okay.		7 relied on and mentioned in your report; correct?	
8 A. Any image -- what I generally do is I'll		8 MR. KREMEN: Objection.	
9 search for images of the product, and I'll try to		9 THE WITNESS: Not to my knowledge. I	
10 zoom in on the content -- the label content,		10 cannot spell it out at this point. Because,	
11 information that's posted on the label.		11 again, I need to see what the title of the patent	
12 Q. Okay.		12 was to clarify it. At this point, looking at	
13 A. But I never had physically the label in		13 patent numbers is kind of like looking at a	
14 my hands.		14 foreign language for me.	
15 Q. Okay. Items No. 7 and 8 contain a list		15 BY MS. PETERSON:	
16 of patents in a published patent application.		16 Q. Sure. Okay. And then the rest of the	
17 Do you see that?		17 items on your list, it's a number of publications;	
18 A. Yes.		18 correct?	
19 Q. Why did you review those?		19 A. That's correct.	
20 A. They were probably to give me foundation		20 Q. And what was the purpose for reviewing	
21 information so that I can evaluate -- I'd have to		21 these?	
22 go back and look at my files -- so that I could		22 A. Again, to familiarize myself more so	
23 evaluate and give a response to the plaintiff as		23 with what nanoemulsions are as well as what	
24 far as what I reviewed. Before I can make a		24 nanotechnology involved. Having done the research	
25 judgment on a thing or give advice to a company,		25 in terms of what BlueWillow was doing as research,	

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Transcript of Edward A. Lemmo, Ph.D.

56 (221 to 224)

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	221		223
1 not necessarily for the commercial aspect but the 2 research work that they were doing, to better 3 familiarize myself so that I can express myself 4 relative to what the nanotechnology and 5 microemulsions in their applications really meant.		1 Q. Okay. So at the bottom of this 2 paragraph, you have a sentence that's underlined 3 where you state that, "By their very nature, 4 nanoemulsion droplets exhibit an electrostatic 5 charge which causes them to repel one-another"--	
6 Q. Okay. And these patents and 7 publications, these are general materials relating 8 to nanoemulsion, not necessarily directed to 9 specific research being conducted by BlueWillow; 10 right?		6 A. Yes. 7 Q. -- correct? 8 A. Yes.	
11 A. Yes, that's correct. 12 Q. Okay. 13 A. It was for my own edification so that I 14 would be able to speak about it.		9 Q. Okay. So when a nanoemulsion is applied 10 to the skin, it exists as individual droplets? 11 A. Yes. 12 Q. And then after application to the skin, 13 they remain as separate droplets on the skin --	
15 Q. Okay. 16 MS. PETERSON: We can take that down. 17 MR. KREMEN: Would it be a good time for 18 a break right now? 19 MS. PETERSON: Sure. We can go off the 20 record. 21 THE VIDEOGRAPHER: We're going off the 22 record. The time is now 4:12 p.m. 23 (Recess from the record.) 24 THE VIDEOGRAPHER: We're back on the 25 record. The time is now 4:24 p.m.		14 A. Right. 15 Q. -- as a result of that electrostatic 16 charge; right? 17 A. Right. I believe that's the way it is. 18 And they would coalescent to a single liquid mass 19 if they were not electrostatically charged. 20 Q. So, in other words, when applied to the 21 skin, they don't form a continuous layer on the 22 skin. They still exist as droplets? 23 A. That is my understanding of how the 24 technology works. Because you have positive and 25 negative charge built into the structure of the	
1 MS. PETERSON: Okay. Let's pull up 2 Exhibit 13, which is Dr. Lemmo's opening expert 3 report. 4 THE REMOTE TECHNICIAN: Stand by. 5 MS. PETERSON: And this one at least has 6 legible page numbers. So hopefully that will help 7 out. But if we could turn to page 8 of the 8 report, which is page 11 of the PDF. 9 BY MS. PETERSON: 10 Q. Okay. So at the top of this page, 11 Section 3, Dr. Lemmo, you included an explanation 12 of nanoemulsion technology, correct? 13 A. That's correct. 14 Q. Why did you include this? 15 A. I wanted to reiterate what I said 16 earlier about those references in that I read -- I 17 read references about the nanoemulsion process, 18 the technology, acting as an interesting delivery 19 system as opposed to a person who was just -- had 20 not pretty much done their homework in reviewing 21 the material. So it was essentially to get a 22 foundation started. 23 Q. Okay. And you understand that NanoBio 24 Protect is a nanoemulsion product? 25 A. Yes.	222	1 nanoemulsion. 2 Q. Okay. Now, you -- we touched on this 3 briefly, but you also relied on reports prepared 4 by Dr. Ermakov and Mr. Burns about some testing 5 that they did -- 6 A. Yes. 7 Q. -- in forming your opinions as stated in 8 your opening report; correct? 9 A. Yes, that's correct. 10 Q. Okay. So on page 9 -- 11 MS. PETERSON: If we can turn to that, 12 please. 13 If you go down a little bit farther. 14 Okay. The paragraph that starts on January 11th. 15 BY MS. PETERSON: 16 Q. About halfway through that paragraph, 17 you state, "I reviewed this report" -- and here 18 we're referring to Dr. Ermakov -- "and found 19 Dr. Ermakov's methodology and conclusions to be 20 sound." 21 A. Yes, that's correct. 22 Q. That's your position? 23 A. Yes. 24 Q. Okay. And then on the next page, you 25 make the same statement regarding Mr. Burns, as	224

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1 well; correct?		1 Dr. Ermakov or Mr. Burns include a CV; correct?	
2 A. That's correct.		2 A. That's correct.	
3 Q. So you also found Mr. Burns' methodology		3 Q. Did you -- have you reviewed or -- did	
4 and conclusions to be sound --		4 you review any résumés or CV for Mr. Burns or	
5 A. Yes.		5 Dr. Ermakov --	
6 Q. -- based on what you reviewed in his		6 A. No, I have --	
7 report?		7 Q. -- prior to preparing your report?	
8 A. Based on his report, yes. As well as		8 A. No, I never checked on their academic	
9 Dr. Ermakov's report.		9 credentials or their employment status.	
10 Q. Okay. And I think we established this		10 Q. So you didn't do anything to investigate	
11 earlier, but you did not have any meetings or		11 their qualifications before relying on their	
12 discussions with Mr. Burns or Dr. Ermakov prior to		12 testing?	
13 preparing your report; right?		13 A. No, I did not.	
14 A. That's correct. I relied solely on the		14 Q. I assume you also did not have any role	
15 written report.		15 or participate in designing the test methods used	
16 Q. Okay. So I assume, then, also that you		16 by Dr. Ermakov and Mr. Burns?	
17 did not participate or make the decision to have		17 A. I had no involvement.	
18 Dr. Ermakov and Mr. Burns conduct the testing?		18 Q. Did you review those test methods or	
19 A. I had no involvement in those decisions.		19 protocols prior to them performing the	
20 Q. And I also assume you did not identify		20 experiments?	
21 Dr. Ermakov or Mr. Burns as candidates to oversee		21 A. No.	
22 and design that testing?		22 Q. And no role in designing the conditions	
23 A. That's correct. I did not know either		23 under which the testing occurred?	
24 one of them.		24 A. I'm sorry, I missed the beginning of	
25 Q. Okay. You anticipated my next question.		25 your statement. Can you just repeat that for me?	
	226		228
1 So you never worked with either one before?		1 Q. You didn't have any role or participate	
2 A. Neither one.		2 in designing the conditions under which the	
3 Q. Okay. Not aware of either of them prior		3 testing occurred?	
4 to reviewing their reports?		4 A. Oh, no, I had absolutely no involvement	
5 A. Not at all.		5 with either one of them.	
6 MR. KREMEN: Um -- okay. Go ahead.		6 Q. Did you have any role or participate in	
7 THE WITNESS: Perhaps -- you know, the		7 the decision to decide that the products should be	
8 only thing that I can say is if they were part of		8 tested on paper and on dried pigskin?	
9 the discussion related to the case against		9 A. No, not at all.	
10 Matrixx Initiatives, it's possible that I read		10 Q. And did you have any role or participate	
11 reports if that was employed. But at this point		11 in any discussions about what equipment should be	
12 I'm not certain. So I can't commit to that.		12 used in the testing?	
13 BY MS. PETERSON:		13 A. No, no involvement.	
14 Q. So if you were aware of them prior to		14 Q. It is your understanding that Mr. Burns	
15 preparing this opening report, it would have been		15 and Dr. Ermakov used different equipment; correct?	
16 in connection with them preparing reports of a		16 A. Yes.	
17 similar nature for use in the Matrixx?		17 Q. Do you know why that is?	
18 A. That's correct. Yes, that's correct.		18 A. I would -- again, this is an assumption	
19 But I did not know either one of them. They are		19 on my part, it's just the manner in which they	
20 complete strangers to me.		20 conduct their tests in their independent	
21 Q. So you were not aware of either of them		21 laboratories. So how Dr. Ermakov did his testing	
22 outside of the work on your matter involving		22 for surface charge versus how Mr. Burns did his	
23 BlueWillow or Matrixx?		23 testing using the equipment for the measurements,	
24 A. That's correct.		24 I had no knowledge of that except for what I read	
25 Q. Okay. Now, neither of the reports by		25 in these reports.	

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1 Q. Okay. So looking then at these 2 statements in -- on pages 9 and 10 of your report, 3 what did you base your conclusion that their 4 methodology was sound?		1 A. I don't know the answer to that, but I 2 would assume that they do that routinely only 3 because of what I witnessed their facilities. 4 Q. And that's something that you learned 5 after preparing your report.	
5 A. Just on what I read. I assumed that 6 their methodology -- one being in a respected 7 university of which I'm a graduate, I'm assuming 8 that he would utilize methodology that would be 9 sound. Mr. Burns worked for -- I believe it's a 10 private laboratory, outside laboratory. In my 11 past experience, I've used outside laboratories 12 for analytical purposes, and I assume that they 13 have the necessary credentialing and 14 certifications that are afforded to these 15 laboratories to be responsible with the results 16 that they provide.		6 A. That's correct. 7 Q. Okay. How did you determine that the 8 appropriate equipment was used by Mr. Burns and 9 Dr. Ermakov at the time that you prepared your 10 opening and reply reports on infringement?	
17 Q. Okay. So, in other words, to confirm 18 that their methodology was sound, you relied on 19 what they contained in their -- of what they 20 provided in their reports?		11 A. I relied exclusively on what they wrote. 12 Q. Okay. 13 A. So I just -- I pretty much just use that 14 as reference that what they were stating was 15 factual.	
21 A. Yes, that's correct.		16 Q. Okay. Bear with me for one second. 17 A. Sure. 18 Q. Do you know when -- okay. So both 19 Mr. Burns and Dr. Ermakov, they both tested Trutek 20 samples as well Blue Willow NanoBio Protect 21 samples; correct?	
22 Q. And you didn't do any other independent 23 investigation to assess the accuracy of the 24 methodology other than what was written in the 25 reports?		22 A. That's correct. 23 Q. Do you know when those samples were 24 manufactured? 25 A. I don't know.	
	230		232
1 A. No, I didn't think that it was necessary 2 for me to do so. I took it at face value that it 3 was reliable. 4 Q. And I don't have the name of his 5 laboratory, but the laboratory that Dr. Burns -- 6 Mr. Burns is associated with, have you ever worked 7 with --		1 Q. Do you know what their expiration date 2 was? 3 A. I don't know. 4 Q. Do you know what lot numbers the samples 5 were that were tested? 6 A. I don't think that they were reported in 7 the body of the reports. They may have had 8 coding, but I offhand at this point can't recall. 9 THE WITNESS: Bless you. 10 MR. KREMEN: Thank you. 11 BY MS. PETERSON: 12 Q. So you don't know if the products -- if 13 they were expired or not at the time of testing?	
8 A. ETS. ETS. 9 Q. ETS. Thank you. 10 A. Yes. 11 Q. Have you ever worked with ETS 12 previously? 13 A. No, not at all. 14 Q. Had you ever heard of ETS? 15 A. No. 16 Q. Do you know what type of testing ETS is 17 typically engaged in? 18 A. I never investigated it in great detail. 19 Q. Do you know how often Mr. Burns or 20 Dr. Ermakov performed tests of the nature 21 described in their reports? 22 A. I did not inquire on that, no. 23 Q. Do you know if Dr. Burns or -- Mr. Burns 24 or Dr. Ermakov typically conduct this type of 25 testing in the normal course of business?		14 A. I assumed that they were not, but I 15 don't know that. 16 Q. Okay. Did Mr. Burns run any 17 standards -- 18 A. In my -- 19 Q. -- over the course of his experiment in 20 order to calibrate the equipment and ensure the 21 accuracy of the test method? 22 A. Actually, I asked him that question, and 23 the answer is yes. 24 Q. And is that reflected in his report? 25 A. I think the reason why I asked him that	

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1 question was I may have been uncertain as far as 2 what was reported in the document itself. So I 3 needed to confirm that based upon my own 4 experience working in a laboratory when I was a 5 graduate student standardizing the equipment that 6 I used on a routine basis. So I simply asked him. 7 Q. And that's a pretty typical thing that 8 you would expect that the equipment would be 9 standardized using --		1 demonstrate for me to understand how he carried 2 out his test. 3 Q. Right. And -- 4 A. And I did the same -- I'm sorry. I did 5 the same with Mr. Burns when I visited his 6 facility. I requested just to witness it so that 7 I can again feel more comfortable in having this 8 conversation.	
10 A. Yes. 11 Q. -- a tool with a known value; right? 12 A. Yes, absolutely. And that's how I was 13 taught. So, you know, you standardize your 14 equipment before you use it. And particularly in 15 a case like this, you really want to have it 16 standardized because you're writing a report 17 regarding a legal matter. 18 Q. And that information was not contained 19 within Mr. Burns' report; correct? 20 A. I don't remember. I don't think so. 21 Q. And that's why you asked him about it at 22 your meeting within the last couple of weeks? 23 A. Yes. It was just to confirm how they go 24 about standardizing their equipment. And I 25 explained my own experience working in the		9 Q. Okay. So, again, that was all after you 10 prepared your reports and formed your -- 11 A. Yes. 12 Q. -- opinions; right? 13 A. Yes, that's correct. 14 Q. So going back to what you said about 15 Dr. Ermakov's report and testing, you mentioned 16 looking at his test results where he compares it 17 to a blank substrate; right? 18 A. That's correct. 19 Q. So is that what you're referring to with 20 respect -- 21 A. Yes. 22 Q. -- to whether Dr. Ermakov -- I mean, 23 that's a control; right? 24 A. That's a control, yes. 25 Q. Okay.	
26 laboratory how I learned to standardize equipment 27 during an instrumentation course as well as during 28 the time that I was in grad school. 29 Q. So at the time that you formed and 30 prepared your opinions on infringement, you had no 31 way of knowing whether Mr. Burns actually 32 calibrated his equipment with a known standard? 33 A. I would assume that he did because he 34 works for what I saw as a reliable company. And 35 Dr. Ermakov, being at Rutgers University -- from 36 my experience at Rutgers University as a grad 37 student there, I know that the equipment routinely 38 gets standardized. It's kind of standard 39 procedure when you're in an institution of that 40 nature. 41 Q. And did Dr. Ermakov's report indicate 42 that he ran any known standards to calibrate the 43 equipment or to ensure the accuracy of the test 44 method? 45 A. I think when you look at the test 46 results where he's comparing it to a blank 47 substrate and then each of the test features, I 48 think there are three or four more, I needed to 49 understand how he arrived at the conclusions that 50 he reached in his result. So I asked him to	234	1 A. But you're talking about standardization 2 of the equipment -- 3 Q. Yeah. 4 A. -- and the routine standard -- that the 5 equipment is functioning accurately. And that's 6 not reflected in that report, to my knowledge. 7 Q. Okay. 8 A. And I don't think he was -- I don't 9 think he needed to indicate that in his -- based 10 upon the nature of his report. It was basically a 11 comparative study. So we assume that everything 12 was standardized. But, again, I can't swear to 13 that. 14 Q. So you're assuming that everything is 15 standardized because you're just comparing the 16 results between two products? 17 A. No, I'm assuming that it's all 18 standardized because of the nature in which it was 19 conducted. At Rutgers University, that's a 20 standard protocol for laboratories. It's not -- 21 you know, it's in the chemistry department, and 22 routinely there's quality control and quality 23 assurance and people who will walk around the 24 laboratory making sure that everything is working 25 correctly.	236

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1 I also think in a commercial laboratory 2 like ETS that they, too, have guidelines for 3 standardization of their equipment before they run 4 any samples for any clients. 5 Q. Right. So your expectation was that 6 they would have run standards to calibrate the 7 equipment, but you can't be certain whether or not 8 they did? 9 A. Yeah, I wasn't there. 10 Q. Okay. So while we're talking about 11 controls, did Dr. Burns run any controls in his 12 experiment? 13 A. Yes. 14 Q. And what were those? What was the 15 control that he ran? 16 A. I believe it was simply the pigskin by 17 itself in the Faraday cup. 18 Q. Okay. And does he -- but he doesn't 19 report the results of any testing of the plain 20 pigskin prior to application of the formulations; 21 correct? 22 A. You know, to be honest, I'd have to look 23 again at the report to see, but I'm assuming the 24 answer is that he did not identify that. 25 Q. I mean, I know in Dr. Ermakov's report			
	238		240
1 he did test the blank paper and reported results? 2 A. Yes. Yes. 3 Q. But I did not see that in Mr. Burns. 4 Okay. 5 A. Yeah, I did not. Yeah. 6 Q. Okay. Going back to Dr. Ermakov, the 7 control that he used, it was just a plain piece of 8 paper; right? 9 A. That's correct. I believe it was kind 10 of like a cardboard or that which you would find 11 like an index card of that nature. 12 Q. Okay. And he was able to detect a 13 surface charge on that substrate; correct? 14 A. That's correct. 15 Q. Would you expect to see a surface charge 16 on untreated paper? 17 A. Yes. 18 Q. Is paper conductive? 19 A. I think liquids are more conductive, but 20 I think that surface charge -- particle charge 21 would be on any surface. 22 Q. Let's -- actually, going back to 23 Mr. Burns, is it your recollection that the 24 controls were not just plain pigskin, but pigskin 25 that had been ionized to neutralize the existing			

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1 will boost that level of charge because of the 2 charge that's existent on the material itself that 3 you're questioning. So you've got the surface -- 4 the substrate as the surface, and then you have 5 the test sample added to half of that piece of 6 paper in the case of Dr. Ermakov.		1 Q. Okay. So you're talking there about an 2 organ like a heart as opposed to specifically 3 human skin; right?	
7 Q. Okay. And is this something that you 8 learned from your conversations with Mr. Burns and 9 Dr. Ermakov?		4 A. Well, if you have to use -- if you have 5 to use an animal model, you really want to have an 6 animal model that is as closely resembling the 7 human in which the agent is going to be tested. I 8 would not be testing, for example, a digestive 9 function of a cow who has a four-compartment 10 stomach and compare that to a human because we 11 only have a one-compartment. So I want to find a 12 molding that is as closely physiologically 13 similar. And I think Mr. Burns made that 14 selection on that basis.	
10 A. It was the result of my visit to ask 11 them to demonstrate it for me. Because this is 12 not something that I have a great deal of 13 experience in, and as a result, I could read the 14 test results and I can understand his conclusion 15 based upon that, but it's very different when you 16 actually witness what the investigator did in the 17 test procedure. Since I had no involvement in 18 requesting the tests or any knowledge whatsoever 19 about the nature of the laboratory that it was 20 done, it was best for me to witness it, and that's 21 what I did.		15 Q. Okay.	
22 Q. That's what you did when you met with 23 them earlier this month?		16 A. But that's a question that you'd 17 probably have to pose to him to better explain it.	
24 A. Yes.		18 Q. Yeah. But I'm wondering about what you 19 did to independently confirm that the methodology 20 was sound with respect to the substrate that was 21 selected here. So it sounds like you did some 22 research on your own in the literature?	
25 Q. Okay.		23 A. I tried to find as much as I could in 24 order to -- again, if you're asking for an opinion 25 from me, I can't just pull it out of thin air. I	
	242		244
1 A. Yes.		1 have to go back and look at references and see 2 what other people may have used in these kind of 3 determinations. And, also, one of my concerns is 4 always is this a standard test? Is this something 5 that routinely if I were going to investigate this 6 as part of my research project, is this the 7 protocol that I would use? That's just my own 8 nature of how I would be investigating things.	
2 Q. Now, both sets of tests, they were 3 conducted at room temperature; correct?		9 Q. Okay. And I have a few follow-up 10 questions there.	
4 A. I believe so, yes.		11 So the literature that you researched, 12 that would be the paper that you've cited in your 13 reply report; correct?	
5 Q. And that's lower than what you would 6 expect for human body temperature?		14 A. That's correct.	
7 A. Yes.		15 Q. Okay.	
8 Q. Now, Mr. Burns used pigskin as a 9 substrate for his testing; right?		16 A. Yes, I think the researcher -- I'm not 17 certain -- it has a three-letter word, Abd or Adb. 18 That's the person that I relied on, yes.	
10 A. That's correct.		19 Q. Okay. So that was something that you 20 did in connection with forming your opinions in 21 your reply report; right?	
11 Q. And at the time that you prepared your 12 report, what did you do to determine whether that 13 was an appropriate substrate for purposes of this 14 test?		22 A. That's correct. That's correct.	
15 A. I simply looked at the literature on the 16 use of either artificial skin or using another 17 example. And my understanding simply from my 18 experience in physiology and my teaching 19 experience, I've been well aware and I've taught 20 about the subject. In the case of valve 21 replacements in hearts, the valves are usually 22 derived from animals such as pig. So it's a 23 suitable physiologically significant tissue to use 24 to demonstrate what would happen in the case of 25 human skin.		23 Q. Now, you also mentioned one of your 24 concerns in research projects is whether something 25 is a standard test. Have you ever had the need to	

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1 measure the surface charge of a pharmaceutical 2 formulation over the course of your career?		1 using. I don't know what the restrictions are or 2 the legalities relative to the types of skin that 3 might be employed in a laboratory setting like 4 ETS.	
3 A. No.		5 Q. Okay. Do you know what part of the pig 6 the skin samples came from?	
4 MR. KREMEN: Objection to form.		7 A. No, I don't.	
5 BY MS. PETERSON:		8 Q. Do you know what the physiological 9 differences are between pigskin and human skin?	
6 Q. So the testing that Mr. Burns and 7 Dr. Ermakov did, you've never had occasion to 8 consider such testing or rely on any such testing 9 apart from your work for Trutek in these matters; 10 right?		10 A. Well, in my reading, it indicates the 11 fact that they are very similar.	
11 MR. KREMEN: Objection to the form of 12 the question.		12 Q. Do you know whether there are any 13 differences between pigskin and human skin, 14 particularly within, like, the area of the nostril 15 and nasal passages?	
13 THE WITNESS: Well, I've never had the 14 opportunity to investigate it like that. That was 15 not something that I've ever done.		16 A. I couldn't really comment. I would have 17 to do another investigation as far as cellular 18 composition of the skin.	
16 BY MS. PETERSON:		19 Q. Now, Dr. Ermakov used paper as a 20 substrate in his testing; right?	
17 Q. Okay.		21 A. That's correct.	
18 A. So no other client has come to me to 19 investigate surface charge.		22 Q. And did you do anything to independently 23 determine whether paper was an appropriate 24 substrate for purposes of this test?	
20 Q. Okay.		25 A. When I reviewed Dr. Ermakov's work, I	
21 A. If that's what you want to know.			
22 Q. Okay. And you never did that over the 23 course of your work through the various companies 24 that you've worked with over your career either; 25 right?			
	246		248
1 A. No, the only closely resembling activity 2 would have been in my instrumentation and my 3 honor's course in chemistry and measuring ion and 4 absorption to services. That would pretty much be 5 the only connection that I can relate to.		1 assumed that it was to establish some degree of 2 baseline that, in fact, the test materials would 3 have a surface charge. So regardless of what he 4 used, I think he probably had evidence that paper 5 would be a good substrate, an adequate substrate 6 to conduct this kind of investigation to establish 7 a baseline for surface charge.	
6 Q. Okay. Now, going back to something else 7 you said, you said it was important to use an 8 animal model that closely resembles or is similar 9 to the intended test subject; correct?		8 I also, when I met with him, asked him 9 if he had done this work previously, and he has. 10 So if he's doing this, he must know that this 11 works appropriately, particularly to establish a 12 baseline. The work by Burns would be a step above 13 the work by Ermakov in establishing it in a more 14 physiological or physiologically similar condition 15 using the pigskin to what you would see in human 16 flesh.	
10 A. That's correct.		17 Q. So when you refer to Dr. Ermakov's work 18 as establishing a baseline, you're referring to 19 the fact that it's measuring surface charge but 20 not on a substrate that really is reflective of 21 how the products are going to be used in -- under 22 actual real life conditions?	
11 Q. Are you aware of the fact that human 12 cadaver skin is also available for testing?		23 A. I think that the purpose of his study 24 was simply to establish whether or not there was a 25 charge and how you are comparing those examples.	
13 A. Yes. And you could also use artificial 14 skin. So there are options that could be used.			
15 Q. Would you find human skin to be a more 16 accurate reflection of how a surface charge will 17 exhibit upon application of these products to 18 human skin as compared to pigskin?			
19 A. I can't really comment on that 20 accurately. So I would say I'm not really 21 certain. I can make assumptions, but one of the 22 key features is really if, in fact, the skin 23 physiologically is going to be the same. And it's 24 also a question of availability, whether or not 25 that's something that the laboratory would be			

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1 So he had to use something. It's similar to what 2 you would do in any kind of experiment. You have 3 to start someplace. 4 Q. Okay. And then all of that explanation 5 that you just got about Dr. Ermakov, again, that 6 was from your conversation with him a couple of 7 weeks ago?		1 results that for the most part the measurements 2 obtained by Dr. Burns and Ermakov were pretty 3 consistent with each other; right? 4 A. Yes. 5 Q. With one exception, do you recall that 6 the results obtained from the measurement by 7 Dr. Burns of the BlueWillow product, that there 8 was actually a pretty wide variation in those 9 results?	
8 A. Yes. 9 Q. That was not information that you were 10 aware of at the time you prepared your reports on 11 infringement; correct? 12 A. No, that's correct. 13 Q. So over the course of your career, when 14 you've used equipment to conduct various tests, is 15 it important to run a number of tests to confirm 16 reliability of the method?		10 A. Yes, that's to be expected. 11 Q. And why is that to be expected? 12 A. There could be any number of factors 13 that can contribute to that. But the purpose of 14 the study was just to establish whether or not 15 there was a surface charge. 16 Q. Okay. 17 A. It wasn't a -- in doing experimentation, 18 there are different goals, and it's either a 19 quantifiable goal or just the identification goal. 20 And the goal in both of these studies, to my 21 knowledge, was to identify the fact that the 22 samples that were tested, in fact, exerted a 23 surface charge.	
17 A. I'm not following your question when you 18 say -- 19 Q. Well, if you wanted to -- let's say you 20 wanted to measure the surface charge of something. 21 Would it be important to you to run the test in 22 multiple replications so that you can ensure -- 23 A. Oh, yes. 24 Q. -- the reliability and precision of the 25 method?		24 Q. So for purposes of your analysis and 25 your opinions, you were relying on the fact that a	
1 A. Yes, absolutely. Absolutely. And, you 2 know, typically, whenever -- at the time when I 3 was conducting research work at Rutgers 4 University, you know, we would run multiple 5 samples so that we would get an average value, and 6 that average value was then statistically analyzed 7 so that we would have a framework. 8 But before we would go to the 9 statistical analysis of it, we had to establish 10 some basics that, in fact, what we were doing was 11 appropriate, that we were getting a reading. So 12 we established that baseline. 13 Q. Okay. And so before relying on the 14 results of that testing, you would run the 15 experiment with a number of replicates, you would 16 determine the average, the standard deviation, and 17 then determine whether those results were 18 statistically significant? 19 A. Yes. 20 Q. Okay. 21 MR. KREMEN: Objection. 22 THE WITNESS: But that wasn't relevant 23 to what he did. 24 BY MS. PETERSON: 25 Q. Now, you recall from reviewing the	250	1 surface charge was measured; correct? 2 A. That's correct. That's my 3 understanding, yes. 4 Q. Okay. You weren't concerned necessarily 5 with what those particular measurements were. 6 A. No. And I wasn't concerned about 7 statistical significance relative to these kinds 8 of trials. If we were to look at things where we 9 were measuring a value that's found in a sample 10 where the reliability of the test protocol that's 11 used is going to give me a closer measure or 12 measurements, as you see in some of the samples, 13 you know, that would be something that I would be 14 interested in. But I don't think that that was 15 the purpose of either one of these trials. 16 Q. Now, if you saw a wide variability in 17 results of the same testing procedure on the same 18 sample, would that suggest to you that there might 19 be some flaw in the method? 20 A. I would first repeat the test just to 21 confirm what I'm witnessing for why there is 22 variability. If it's a factor that I can control 23 or correct, I would execute that factor to correct 24 the problem. So with both of these -- even though 25 there is variability in that test that was done by	252

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1 Burns, the point is that this still was surface		1 A. Because that was part of the '802	
2 charge and --		2 patent's claim, is that it has this electrostatic	
3 Q. No, I understand. You were still just		3 charge and it is cationic.	
4 looking --		4 Q. But if all you were interested in	
5 A. Yes.		5 knowing was that the products exhibited an	
6 Q. -- for a surface charge measurement, but		6 electrostatic charge, why did it matter to you	
7 I --		7 that they were of the same order of magnitude?	
8 A. That's all it was.		8 A. Just to see how closely resembling they	
9 Q. I'm asking a more basic question. If		9 are. The cation that is used, if it's	
10 you see wide variability, that could suggest a		10 benzalkonium chloride, and the quantification	
11 flaw in the method; right?		11 therein, should be similar if the amounts are the	
12 A. It could. It could.		12 same.	
13 Q. It could also suggest that the		13 Q. And why was it important to you to know	
14 particular method is not very accurate?		14 whether the surface electrostatic charge was	
15 A. It could question the accuracy. It can		15 similar between NanoBio Protect and NasalGuard?	
16 question even the conditions in which the study		16 A. Well, because the claims are being made	
17 was conducted.		17 about the product. And that's the basis of this	
18 Q. And it could also question the		18 whole proceeding, is that the two items have	
19 reliability of the method; right?		19 similarity. NanoBio and Trutek's NasalGuard	
20 A. Well, considering the nature of what was		20 products, they are similar.	
21 found in the one study -- or the one sample versus		21 Q. Okay. So when you just referred to the	
22 the others, there seemed to be more consistency in		22 claims being made about the product, you're not	
23 the other study -- or the other samples as		23 talking about the patent claims here. You're	
24 compared to the one of the NanoBio product.		24 talking about the statements made about the	
25 The problem there is, at least I		25 products on, like, the websites and non-product	
	254		256
1 investigated this a little bit further, in looking		1 labeling; right?	
2 at things like the water content, the products		2 A. Right. Right.	
3 reflect the fact that they utilized water. And in		3 Q. I just wanted to get some terminology	
4 my investigation, of course this is after the		4 clear because we have "claims" used in two	
5 fact, but looking at things like purified water		5 contexts.	
6 versus distilled deionized water, deionized water		6 A. Yeah.	
7 would be removing those cations, whereas purified		7 Q. So how did you use the conclusion that	
8 water may, in fact, contribute some cations. So		8 NanoBio Protect and Trutek's NasalGuard products	
9 that might be a factor. But, again, I can't		9 exhibited an electrostatic charge of the same	
10 confirm that because I didn't do any additional		10 order of magnitude in reaching your opinion on	
11 testing.		11 infringement?	
12 Q. Okay. Now, the conclusion that you		12 MR. KREMEN: Objection to form.	
13 relied on from the Burns and Ermakov testing was		13 THE WITNESS: I simply relied on the	
14 that both the Trutek products and the NanoBio		14 documentation that was supplied --	
15 Protect product exhibited a surface charge, and		15 BY MS. PETERSON:	
16 that surface charge was of the same order of		16 Q. Okay.	
17 magnitude; correct?		17 A. -- by both of the researchers.	
18 A. That's correct.		18 Q. But how did you use that in reaching	
19 Q. And why was it important to you that the		19 your opinion? How was it relevant to your opinion	
20 surface charge was of the same order of magnitude		20 on infringement?	
21 between the two products?		21 A. Because you have to see whether or not,	
22 A. Just to determine the amount. That was		22 in fact, if the existence of the patent -- the	
23 pretty much it. Is it there or not? Does it		23 '802 patent preceded the marketing of the product	
24 contribute any cationic charge?		24 to NanoBio, then that NanoBio product is	
25 Q. Okay.		25 infringing on the patented protected product of	

Transcript of Edward A. Lemmo, Ph.D.

65 (257 to 260)

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	257		259
1 Trutek. I'm looking at it from that standpoint.		1 particular electrostatic charge.	
2 Q. Okay. Let me try asking the question		2 A. Quantified?	
3 again. So you relied on the conclusion from Burns		3 Q. Correct.	
4 and Ermakov that Trutek's products and		4 A. No, it doesn't.	
5 BlueWillow's product exhibited an electrostatic		5 Q. Okay.	
6 charge of the same order of magnitude; correct?		6 A. There's no quantification that's listed	
7 A. That's correct.		7 here, no.	
8 Q. And how did you use that information to		8 Q. And you would also agree that the	
9 determine whether NanoBio Protect satisfies the		9 results of the Burns and Ermakov testing actually	
10 elements of the '802 patent claims?		10 show that the electrostatic charge exhibited by	
11 A. Because of where it's stated in the '802		11 the Trutek and BlueWillow products was actually	
12 patent. The '802 patent talks about the		12 different; right?	
13 electrostatic charge. That's a significant factor		13 A. Quantifiably, yes.	
14 for the methodology of how that product works.		14 Q. Right.	
15 Q. The '802 patent claims, they don't		15 A. But, again, I go back to my statement	
16 require an electrostatic charge; correct?		16 that it wasn't a quantification. It was more of	
17 MR. KREMEN: Objection.		17 an identification that both products exhibited the	
18 BY MS. PETERSON:		18 electrostatic charge when applied to the	
19 Q. That language is not in the claims;		19 substrate.	
20 right?		20 Q. Okay.	
21 A. I have to go back and take a look		21 A. That's how I understood it.	
22 exactly. I'm sorry, it's late in the day.		22 Q. Okay. So if your analysis was focused	
23 Q. Yeah, sure. No problem. We can pull		23 on determining whether NanoBio Protect --	
24 that back up. Do you have that copy of the patent		24 A. Yes.	
25 handy still?		25 Q. -- infringes the '802 patent claims, why	
	258		260
1 THE REMOTE TECHNICIAN: I'm sorry,		1 was it relevant to you that NanoBio Protect had a	
2 Ms. Peterson, are you speaking to me if I have		2 surface electrostatic charge of the same order of	
3 that copy handy?		3 magnitude as NasalGuard?	
4 MS. PETERSON: No, I was asking		4 A. Well, it would probably -- again, it	
5 Dr. Lemmo.		5 would probably reflect the composition of the	
6 THE WITNESS: Oh, I don't have it -- no,		6 NanoBio Protect relative to the amount of cation	
7 I don't have it physically near me. That's why		7 that's being contributed by the ingredients of the	
8 I'm just -- I'm rummaging around.		8 NanoBio Protect. So, in other words, if I look at	
9 MS. PETERSON: Okay. Then, yeah, can we		9 the benzalkonium chloride content of both	
10 pull up on the screen Exhibit 2 and go to --		10 products, they're both going to contribute cation.	
11 THE WITNESS: Oh, I found it. All		11 And that's going to be a significant factor as far	
12 right.		12 as how that product will work.	
13 THE REMOTE TECHNICIAN: Of course I can		13 Q. Okay. So, in other words, you're	
14 pull it up.		14 assuming that because the two products had the	
15 MR. KREMEN: He has it.		15 same order of magnitude of electrostatic surface	
16 THE WITNESS: I have it.		16 charge, they had the same ingredients?	
17 BY MS. PETERSON:		17 MR. KREMEN: Objection.	
18 Q. Okay. Let's look at Claim 1.		18 THE WITNESS: I can't make that	
19 A. Yeah.		19 assumption because there are multiple ingredients	
20 Q. It talks about electrostatically		20 in both products.	
21 inhibiting; right?		21 BY MS. PETERSON:	
22 A. Right. Right.		22 Q. But because they have the same order of	
23 Q. And electrostatically attracting; right?		23 magnitude, you're assuming that the products	
24 A. Right.		24 operate in the same manner?	
25 Q. But the claims don't require a		25 A. They have similarity.	

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Transcript of Edward A. Lemmo, Ph.D.

66 (261 to 264)

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1 Q. Okay. And so you considered -- so, in 2 other words, you considered the surface 3 electrostatic charge of NasalGuard and how it 4 operates as part of your analysis of whether 5 NanoBio Protect practices the elements of the '802 6 patent claims?		1 the question of conductivity versus surface charge 2 and whether they measured conductivity or they 3 measured surface charge.	
7 A. Yes.		4 Q. Okay.	
8 Q. Okay. Let's take a look at your reply 9 report now.		5 A. And so I needed clarification to 6 understand what they tested and why Dr. Amiji 7 thought that it was the measurement of 8 conductivity as opposed to surface charge.	
10 MR. KREMEN: Which one?		9 Q. So to just break that down a little bit, 10 the Bernardi paper that you cite on page 8, that's 11 related to assessing the stability of 12 nanoemulsions; right?	
11 MS. PETERSON: It was marked as 12 Exhibit 15.		13 A. Yes. Yes.	
13 MR. KREMEN: Okay. Exhibit 15.		14 Q. And one of the ways that the stability 15 was measured or assessed was by measuring the 16 conductivity of the nanoemulsion; right?	
14 THE REMOTE TECHNICIAN: Would you like 15 me to screen share that?		17 A. Right. And, again, it depends on how 18 the electrode -- if the electrode is actually 19 touching the surface of the material or it's 20 somewhere in proximity to the material. And 21 that's the way I understand the difference between 22 the two.	
16 MS. PETERSON: Yes, please.		23 Q. Okay. But this was for the purpose of 24 assessing the stability of the product, right, not 25 determining whether there was a charge destiny?	
17 THE WITNESS: Yes, please.			
18 MR. KREMEN: His reply report, 15?			
19 Yeah, okay. Yeah, noninfringement. Okay.			
20 MS. PETERSON: And if we could go to 21 page 7, which is page 8 of the PDF.			
22 BY MS. PETERSON:			
23 Q. You see here we have a section titled 24 "Charge Destiny Measurement Theory"?			
25 A. Yes.			
	262		264
1 Q. Okay. The explanation that you provided 2 in this section, is that based on your own 3 personal knowledge, or did you obtain this 4 explanation from materials that you reviewed?		1 A. Yes.	
5 A. A combination of things. The materials 6 that I reviewed, the ETS model equipment, the 7 indicator that it was employed. So I relied 8 primarily on that.		2 Q. Okay. Yeah, I think your charge destiny 3 discussion on page 7 might be separate from why 4 you cited Bernardi; is that correct?	
9 Q. You mean you relied primarily on the --		5 A. Yeah, it's possible that, you know, at 6 the time I was trying to link a few factors 7 together.	
10 A. Written materials.		8 Q. Okay. So just to go back to the section 9 where you explain charge destiny measurement 10 theory, just to confirm, you did look at 11 literature, but that's not cited here in your 12 report; right?	
11 Q. -- explanation of the equipment used in 12 Mr. Burns' report?		13 A. Yes, that's correct. This is that which 14 I found out in the literature.	
13 A. I relied on Mr. Burns' report and what I 14 could find also to complement that in the 15 literature.		15 Q. But the literature that you relied on is 16 not identified; right?	
16 Q. Okay. Now, whatever you found in the 17 literature, you don't have it cited here; right?		17 A. Yes, that's correct. It's not 18 identified in my report.	
18 A. Sometimes I do. Sometimes I don't. And 19 I think in this particular case I did not cite 20 anything except for the question as far as 21 Bernardi, there was a paper that spoke about 22 nanoemulsions. And a copy of that paper is 23 attached. That's on the following page.		19 Q. Okay. Now, that Bernardi paper, the 20 particular oil-in-water nanoemulsion assessed in 21 that paper, that was a rice bran oil 22 nanoemulsion?	
24 But I think much of what I wrote in 25 reply to Dr. Amiji, because Dr. Amiji brought up		23 A. Yes.	
		24 Q. And, again, there was no discussion in 25 that paper of measuring electrostatic charge of	

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67 (265 to 268)

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	265		267
1 the nanoemulsion; right?		1 about what skin -- alternative skin models might	
2 A. No, it was mostly reflective of		2 be appropriate for measuring electrostatic charge	
3 Dr. Amiji's reference to conductivity. And, you		3 of a product applied to human skin; right?	
4 know, I included the Bernardi paper really in the		4 A. No, that's correct.	
5 statement that precedes where I indicate in 2011		5 Q. Okay. Let's move forward to page 10 of	
6 that conductivity of the nanoemulsion is usually		6 your reply report.	
7 measured to determine the stability. The testing		7 A. Sure.	
8 was not intended -- or at least what I was trying		8 Q. Okay. And here we have a situation that	
9 to express was that the testing that was done in		9 we have titled as "Admissions Made Directly By	
10 the two laboratory settings was not to determine		10 BlueWillow"; correct?	
11 stability. It was to determine the presence of		11 A. Yes, that's correct.	
12 the charge.		12 Q. Okay. And this would be the various	
13 Q. Okay. So Bernardi measured conductivity		13 statements that you identified on BlueWillow's	
14 to assess stability of the nanoemulsion?		14 website; correct?	
15 A. Yes. Yes.		15 A. Yes, you're correct.	
16 Q. And you cited the Bernardi paper to		16 Q. Okay. You didn't review any other	
17 support your understanding that Burns and Ermakov		17 documents showing any testing or providing any	
18 were testing surface charge, not conductivity?		18 other information to substantiate that the product	
19 A. That's correct.		19 operates in a manner described by BlueWillow on	
20 Q. Okay. And you're aware that -- never		20 its website; right?	
21 mind. We can move on to [sic] that.		21 A. No, I did not see that.	
22 Now, another paper that you mentioned		22 Q. Okay. We can go to the next page. This	
23 earlier -- and it's cited on the next page of your		23 is page 11 of your reply report. There are four	
24 report if we move forward a page.		24 bullet points listed. And these are statements	
25 So on page 8, in the second full		25 that you relied on from Nano -- from the NanoBio	
	266		268
1 paragraph, this is your discussion of that -- or		1 Protect website; correct?	
2 sorry, third full paragraph --		2 A. Yes, from BlueWillow's website on the	
3 MS. PETERSON: If you scroll down some		3 product NanoBio.	
4 more.		4 Q. Okay. So -- hang on a second.	
5 BY MS. PETERSON:		5 That's interesting. You have four	
6 Q. This is the paper that you mentioned		6 statements listed on page 10 of your -- never	
7 regarding alternative skin models by --		7 mind.	
8 A. Yes.		8 You've got four bullet points listed on	
9 Q. -- Abd?		9 your opening report, but they don't match up with	
10 A. Abd, yes. I don't --		10 the same four bullet points listed in your reply	
11 Q. Abd?		11 report, but I think we can use this.	
12 A. I don't know how they pronounce it, but		12 A. Yeah, and it's possible what I was	
13 I -- Abd, I would say.		13 addressing at the time -- at different times that	
14 Q. Okay. Now, you understand that this		14 they were submitted.	
15 paper is directed to assessing whether it's		15 Q. Okay. So looking at the third bullet	
16 appropriate to use alternative skin models for		16 point here, it says, "Dry skin allows germs to	
17 assessing drug permeation through the skin; right?		17 penetrate. Nanodroplets hydrate the skin,	
18 A. Yes. Yes.		18 preventing dryness and cracking"; right?	
19 Q. So, in other words, that's the ability		19 A. Yes.	
20 of a drug or a formulation to pass through the		20 Q. And presumably that reference to the	
21 various layers of the skin into the bloodstream?		21 nanodroplets, that would be the nanodroplets of	
22 A. Right. Right. My goal was to simply		22 the NanoBio Protect product?	
23 state that you can use animal models other than		23 A. Yes, because I believe it comes directly	
24 using human skin.		24 from their website.	
25 Q. Okay. This paper doesn't say anything		25 Q. Okay. So here BlueWillow is explaining	

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68 (269 to 272)

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	269		271
1		1	component parts that will add to protecting and
2		2	hydrating the skin.
3		3	Q. Okay.
4		4	A. So it's not going to irritate. So there
5		5	are similarities, definite similarities,
6		6	intentional or otherwise, but I'm recognizing the
7		7	similarities.
8		8	Q. Okay. But these statements don't
9		9	reference a thin film being used to trap or hold
10		10	particles; correct?
11		11	A. No, that's correct.
12		12	Q. Okay. And you would also agree that
13		13	hydrating the skin to prevent germs from entering,
14		14	that that's not the same as creating a physical
15		15	barrier that blocks those germs from entering?
16		16	MR. KREMEN: Objection to the form of
17		17	the question.
18		18	THE WITNESS: Can you repeat that or
19		19	restate it?
20		20	BY MS. PETERSON:
21		21	Q. Would you also agree that hydrating the
22		22	skin to prevent germs from penetrating the skin,
23		23	that that's a different mechanism of action from
24		24	creating a physical barrier on the skin to prevent
25		25	the germs from going any farther?
	270		272
1	'germs to penetrate"; right?	1	MR. KREMEN: Same objection.
2	A. Correct.	2	THE WITNESS: Well, from going farther
3	Q. Okay. So that impermeable -- that's	3	and setting up -- setting up a barrier so that
4	what we're talking about when you referenced	4	they don't leave the treated surface to enter the
5	earlier about having adequate impermeability to	5	nasal passage.
6	create a physical barrier that prevents the germs	6	BY MS. PETERSON:
7	from penetrating; correct?	7	Q. Okay.
8	A. That's correct.	8	A. My concern was not focused on protecting
9	Q. Okay.	9	dry skin as a vehicle or an entry point for
10	MS. PETERSON: Now, if you can just go	10	microorganisms to invade. The goal, or at least
11	up a little bit more so we can see those bullet	11	the way I'm understanding it, is the role of the
12	points again.	12	two products in preventing the inhalation of the
13	BY MS. PETERSON:	13	harmful particles. So you see the similarities.
14	Q. Here, wouldn't you agree that BlueWillow	14	There are --
15	is saying that its product is operating to prevent	15	Q. Yeah, I see the similarity in that both
16	germs from penetrating the skin, not by creating	16	prevents germs from entering the system.
17	an impermeable thin film or a physical barrier,	17	A. Right.
18	but rather by hydrating the skin; right?	18	Q. But do you agree with me that they are
19	A. Again, what we're talking about is a	19	prevented from entering the system through
20	product that's intended not as a skin protective,	20	different physical means?
21	but as a product that is going to help trap	21	A. Yes, that's correct. One is a
22	contaminants from entering the nasal passage.	22	nanoemulsion, and the other one is not identified
23	While, yes, this is going to have a benefit in	23	as an emulsion. It's a gel.
24	hydrating the skin, but if you go back to the '802	24	Q. Okay.
25	patent with the formulations, there is also	25	A. So physically, when you look at the

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69 (273 to 276)

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	273		275
1 products or at least -- I don't have that product.		1 And then let's mark as Exhibit 20 a copy	
2 I don't have the physical product NanoBio. So I		2 of the Bernardi paper. This is item No. 14.	
3 don't know what [inaudible].		3 (Lemmo Deposition Exhibit 20 was marked	
4 Q. Okay. I think we're talking about two		4 for identification and attached to the	
5 completely separate things here. The two things		5 transcript.)	
6 you were envisioning in your mind were NanoBio		6 THE REMOTE TECHNICIAN: Stand by.	
7 Protect and then Trutek's NasalGuard?		7 BY MS. PETERSON:	
8 A. Right.		8 Q. Dr. Lemmo, do you recognize Exhibit 20	
9 Q. Okay. I'm asking about something		9 as a copy of the Bernardi paper that you cited and	
10 completely different.		10 attached to your reply expert report?	
11 A. Okay. All right. Let's go back over		11 A. Yes.	
12 that.		12 Q. Great. Okay.	
13 Q. I'm just asking whether -- I'm asking		13 MS. PETERSON: Next let's mark as	
14 whether hydrating the skin to prevent germs from		14 Exhibit 21 a copy of the Rolf patent application,	
15 penetrating is a different mechanism of action		15 which is item No. 17 in my materials.	
16 from creating a physical barrier on the skin?		16 (Lemmo Deposition Exhibit 21 was marked	
17 A. Yes.		17 for identification and attached to the	
18 Q. Okay.		18 transcript.)	
19 A. Yes.		19 BY MS. PETERSON:	
20 MS. PETERSON: Let's go off the record.		20 Q. Dr. Lemmo, do you recognize Exhibit 21	
21 THE VIDEOGRAPHER: We're going off the		21 as a copy of United States Patent Application	
22 record. The time is now 5:37 p.m.		22 Publication No. U.S. 2004/0071757 issued to Rolf?	
23 (Recess from the record.)		23 A. Yes.	
24 THE VIDEOGRAPHER: We're back on the		24 Q. And this is the Rolf application that	
25 record. The time is now 5:46 p.m.		25 you addressed in your responsive report; correct?	
	274		276
1 BY MS. PETERSON:		1 A. That's correct.	
2 Q. Okay. Dr. Lemmo, I appreciate all of		2 Q. Okay.	
3 your time today. I know it's been a long day.		3 MS. PETERSON: We can take that down.	
4 I'm almost done. I just have a few other little		4 One final document. Let's mark as	
5 housekeeping things to finish up on.		5 Exhibit 22 a copy of -- it's titled 'Declaration	
6 A. Fine. That's fine.		6 Lemmo.' This is the last document that I	
7 MS. PETERSON: Can we please mark as --		7 uploaded.	
8 sorry, I just had a helicopter flying overhead.		8 (Lemmo Deposition Exhibit 22 was marked	
9 MR. KREMEN: We're not going to mark		9 for identification and attached to the	
10 that.		10 transcript.)	
11 MS. PETERSON: Can we please mark as		11 MR. KREMEN: What is it specifically?	
12 Exhibit 19 a copy of the Abd paper.		12 Oh, okay. That's for the Matrixx case.	
13 (Lemmo Deposition Exhibit 19 was marked		13 BY MS. PETERSON:	
14 for identification and attached to the		14 Q. Yeah. So, Dr. Lemmo, do you recognize	
15 transcript.)		15 Exhibit 22 as a copy of a declaration that you	
16 MS. PETERSON: This is item No. 13 in my		16 prepared in connection with the Matrixx litigation	
17 materials, Jennifer.		17 pending in New Jersey?	
18 THE REMOTE TECHNICIAN: Yes, stand by.		18 A. Yes.	
19 BY MS. PETERSON:		19 MR. KREMEN: Can you go down to the	
20 Q. Okay. Dr. Lemmo, do you recognize		20 signature page just to make sure that --	
21 Exhibit 19 as the paper by Eman Abd that you cited		21 MS. PETERSON: Yeah, I was going to get	
22 and attached to your reply expert report?		22 to that, Stan.	
23 A. Yes, I do.		23 MR. KREMEN: I want to make sure that he	
24 Q. Okay.		24 identifies it because it's been a long time.	
25 MS. PETERSON: We can take that down.		25 MS. PETERSON: Sure.	

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70 (277 to 280)

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	277		279
1 So can we go to the final page,		1 BY MS. PETERSON:	
2 please -- actually, not the final page. Go to		2 Q. Okay. So one of the documents that you	
3 page 7 of the PDF.		3 reviewed as part of your investigation was the	
4 BY MS. PETERSON:		4 "Determination of Surface Electrostatic Charge On	
5 Q. Dr. Lemmo, that's your signature on --		5 Nasal Application Test Products - Test Conducted	
6 A. That's --		6 and Report Prepared by Dr. Alexei Ermakov."	
7 Q. -- page 7; correct?		7 Do you see that?	
8 A. Yes, that's my signature.		8 A. Yes.	
9 Q. This declaration was executed on		9 Q. Okay. So based on this, is it your	
10 January 23rd, 2020; correct?		10 understanding that you also received a copy of and	
11 A. That's correct.		11 reviewed the results of Dr. Ermakov's testing of	
12 Q. Okay.		12 the electrostatic charge of the NasalGuard and	
13 MS. PETERSON: Can we go back up to the		13 Matrixx products?	
14 top of this document.		14 A. Yes.	
15 BY MS. PETERSON:		15 Q. Okay. And then looking at the next item	
16 Q. Do you see up at the top here that		16 in the list, it's identified as "Surface	
17 Amirali Haidri is identified on this document?		17 Electrostatic Charge Evaluation of Nasal	
18 A. Yes.		18 Application Products - Technical Report," prepared	
19 Q. Did you have any discussions or		19 by Shane Burns of Electro-Tech Systems; right?	
20 conversations or meetings with Mr. Haidri in		20 A. Correct.	
21 connection with the preparation of this		21 Q. So based on this, is it also your	
22 declaration?		22 recollection and understanding that you received a	
23 A. No.		23 copy of and reviewed the results of Mr. Burns'	
24 Q. Okay.		24 testing of the electrostatic charge of the	
25 MR. KREMEN: May I clarify something		25 NasalGuard and Matrixx products?	
	278		280
1 just for clarification? Amirali Haidri was a		1 A. Yes.	
2 local counsel in this case. I was lead counsel --		2 Q. Okay.	
3 MS. PETERSON: Okay. Thank you.		3 MS. PETERSON: Thank you, Dr. Lemmo. I	
4 MR. KREMEN: -- out of state.		4 do not have any further questions for you.	
5 MS. PETERSON: Okay. Thank you,		5 THE WITNESS: Thank you.	
6 Mr. Kremen.		6 MR. KREMEN: Okay. Let's see, who am I	
7 Can we scroll to page 3 of this		7 talking to? Jennifer? Can you go up --	
8 declaration.		8 MS. PETERSON: Stan, do you have any	
9 BY MS. PETERSON:		9 questions for the witness?	
10 Q. Okay. And here in paragraph 8 of your		10 MR. KREMEN: No, no. I'm sorry, I	
11 declaration, Dr. Lemmo, you've provided a list of		11 thought we were off the record.	
12 documents that you reviewed as part of your		12 MS. PETERSON: Yeah. So --	
13 investigation; correct?		13 THE VIDEOGRAPHER: No, we haven't closed	
14 A. That's correct.		14 out the record just yet.	
15 Q. And then if you go down and look at the		15 MR. KREMEN: I'm sorry.	
16 eighth bullet point, you see the --		16 MS. PETERSON: So I'm done. It sounds	
17 MR. KREMEN: What line?		17 like Mr. Kremen doesn't have any questions. So I	
18 MS. PETERSON: Bullet point 8. It's the		18 think we can conclude the deposition.	
19 eighth one down on the list. It's identified		19 THE WITNESS: Okay. So I can sign off?	
20 as --		20 Have a great day. Thank you.	
21 MR. KREMEN: There's a line number. So		21 THE VIDEOGRAPHER: All right. Just a	
22 if you could point out the --		22 moment, please.	
23 MS. PETERSON: Line 13.		23 This marks the end of the deposition of	
24 MR. KREMEN: Okay.		24 Dr. Edward A. Lemmo. We're going off the record.	
25		25 The time is now 5:55 p.m.	

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	281		283
1 (Off the record at 5:55 p.m.)		1 STATE OF MARYLAND)	
2		2 ss:	
3		3 COUNTY OF MONTGOMERY)	
4		4	
5		5 I, Matthew Goldstein, Notary Public	
6		6 within and for the State of Maryland, do hereby	
7		7 certify:	
8		8	
9		9 That I reported the proceedings in the	
10		10 within entitled matter, and that the within	
11		11 transcript is a true record of said proceedings.	
12		12	
13		13 I further certify that I am not related	
14		14 to any of the parties to the action by blood or	
15		15 marriage, and that I am in no way interested in	
16		16 the outcome of this matter.	
17		17	
18		18 IN WITNESS WHEREOF, I have hereunto set	
19		19 my hand this 24th day of October, 2022.	
20		20	
21		21 	
22		22 Matthew Goldstein, RMR, CRR	
23		23	
24		24	
25		25	
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1 ACKNOWLEDGEMENT			
2			
3 STATE OF MARYLAND)			
4		ss	
5 COUNTY OF MONTGOMERY)			
6		I, EDWARD LEMMO, PH.D., hereby	
7		certify, I have read the transcript of my	
8		testimony taken under oath in my deposition of	
9		October 24, 2022; that the transcript is a true,	
10		complete and correct record of what was asked,	
11		answered and said during this deposition, and that	
12		the answers on the record as given by me are true	
13		and correct.	
14			
15		EDWARD LEMMO, PH.D.	
16			
17			
18 Sworn and subscribed to before me			
19 this ____ day of _____, 2022.			
20			
21		Notary Public	
22			
23			
24			
25			